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# THE RACE TO PATENT THE SARS VIRUS: THE *TRIPS AGREEMENT* AND ACCESS TO ESSENTIAL MEDICINES

MATTHEW RIMMER\*

*[This article considers the race to sequence the Severe Acute Respiratory Syndrome virus ('the SARS virus') in light of the debate over patent law and access to essential medicines. Part II evaluates the claims of public research institutions in Canada, the United States, and Hong Kong, and commercial companies, to patent rights in respect of the SARS virus. It highlights the dilemma of 'defensive patenting' — the tension between securing private patent rights and facilitating public disclosure of information and research. Part III considers the race to patent the SARS virus in light of wider policy debates over gene patents. It examines the application of such patent criteria as novelty, inventive step, utility, and secret use. It contends that there is a need to reform the patent system to accommodate the global nature of scientific inquiry, the unique nature of genetics, and the pace of technological change. Part IV examines the role played by the World Trade Organization and the World Health Organization in dealing with patent law and access to essential medicines. The article contends that there is a need to ensure that the patent system is sufficiently flexible and adaptable to accommodate international research efforts on infectious diseases.]*

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## I INTRODUCTION

Severe Acute Respiratory Syndrome ('SARS')<sup>1</sup> is a form of atypical pneumonia caused by a new strain of coronavirus ('the SARS virus').<sup>2</sup> It was first reported in the Guangdong province in southern China in November 2002. The illness was first identified by Dr Carlo Urbani, an infectious diseases specialist for the World Health Organization ('WHO'). He found that a patient in Vietnam was suffering from high fever, coughing and shortness of breath. Dr Urbani tragically lost his life to the disease a few weeks later. The outbreak spread from China to the important trade and transport hub, Hong Kong. From there, the illness was further spread by international air travel to another 19 countries, including Taiwan, Singapore, Canada, Vietnam, the Philippines and the United States. The WHO reported that there were 8098 known cases and 774 deaths attributable to the SARS virus in the period between 1 November 2002 and 31 July 2003.<sup>3</sup> The public health epidemic had a significant impact upon the global economy — especially in relation to trade, transport and tourism.<sup>4</sup> It has been variously represented as a medieval plague, a medical disaster and an economic blight.<sup>5</sup>

The rapid discovery of the SARS virus was coordinated by the WHO in Geneva. An international team of scientists and researchers was led by Klaus Stöhr, a virologist at the WHO. Stöhr comments that a closed network was established, in which data and information was shared within the group.<sup>6</sup> He explains the nature of the collaboration:

All laboratories asked to join agreed to do so and to work according to a set of rules on confidentiality of data. These rules specified that data and information shared among the members of the research project would be used only to advance the project in a collaborative way. Specific scientific data could be shared outside the network with the approval of the laboratory from which the data or other

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<sup>1</sup> For an introduction to the scientific work on the SARS virus, see WHO, *Severe Acute Respiratory Syndrome* (2004) <<http://www.who.int/csr/sars/en>> at 1 October 2004; and Science, *Special Online Collection: The SARS Epidemic* (2004) <<http://www.sciencemag.org/feature/data/sars>> at 1 October 2004.

<sup>2</sup> *Merriam-Webster Medical Dictionary* (2002): 'A coronavirus is any of a family (Coronaviridae) of single-stranded RNA viruses that have a lipid envelope with club-shaped projections and include some causing respiratory symptoms in humans'.

<sup>3</sup> The case fatality ratio for SARS was 9.6 per cent of all cases diagnosed. The worst affected countries included China, with 5327 diagnosed cases and 349 deaths; Hong Kong, with 1755 diagnosed cases and 299 deaths; Taiwan, with 346 diagnosed cases and 37 deaths; and Singapore, with 238 diagnosed cases and 33 deaths. Across the Pacific, Canada was also severely affected, with 251 cases and 43 deaths: Communicable Disease, Surveillance and Response, WHO, *Summary of Probable SARS Cases with Onset of Illness from 1 November 2002 to 31 July 2003* (2003) <[http://www.who.int/csr/sars/contry/table2003\\_09\\_23/en](http://www.who.int/csr/sars/contry/table2003_09_23/en)> at 1 October 2004.

<sup>4</sup> Jong-Wha Lee and Warwick McKibbin, 'Globalization and Disease: The Case Of SARS' (Working Paper No 2003/16, Division of Economics, Research School of Pacific and Asian Studies, The Australian National University, 2003) 8.

<sup>5</sup> Abraham Verghese, 'The SARS Epidemic: The Metaphor of Blight', *The Wall Street Journal* (New York, US), 13 May 2003, A18. See also Susan Sontag, *Illness as Metaphor* (1978).

<sup>6</sup> The WHO's Global Outbreak Alert and Response Network was instrumental in the response to the SARS virus. See Bruce Sterling, 'Guns, Germs, and Software: A Networked Strategy Can Defeat Epidemics — If the World Will Let It' (2004) 12 *Wired Magazine* 4.

information originated ... Such open sharing among academic competitors required trust and willingness to work together.<sup>7</sup>

Scientists isolated a virus from patients who had SARS and then used several laboratory methods to look further at the agent. Examination by electron microscopy revealed that the virus had the distinctive shape and appearance of coronaviruses. Tests of blood specimens from patients with SARS showed that the patients appeared to have been infected recently with this coronavirus. Other tests demonstrated that a coronavirus was present in a variety of specimens from patients, including nose and throat swabs. Genetic analysis has raised questions about the origin of the SARS virus, including the possibility of an animal origin, such as the civet cat.<sup>8</sup>

The network of institutions involved in SARS research has been hailed as a case study in international scientific collaboration. There was, however, some competition amongst the research groups to secure credit and commercial rights to their findings. Teams of scientists in Canada, Hong Kong and the US were able to sequence the SARS virus with remarkable speed.<sup>9</sup> A number of public research institutions filed provisional patent applications in respect of the complete genetic sequence of the coronavirus. The main contenders included the British Columbia Cancer Agency ('BCCA'), the US Centers for Disease Control and Prevention ('CDC'), and The University of Hong Kong ('HKU'). The detailed claims in these applications, although not yet publicly available, are reported to be sufficiently broad to allow their holders to claim rights in most diagnostic tests, drugs, or vaccines that have been or would be developed to cope with the outbreak.

This race to patent the SARS virus deserves closer analysis because of the wider debates about gene patenting and public health that it sparked in the international media.<sup>10</sup> The case study provides a vivid illustration of the sometimes arid economic debate as to whether patent races are an efficient means of allocating resources in the marketplace.<sup>11</sup> There are several positions discernible in the debate: the entrepreneurialism of biotechnology companies; the pragmatism of research institutions; the reformist tinkering of academics; and the ethical and moral objections of patent abolitionists. First of all, commercial companies argued that a strong patent system was essential to promote private investment and research into diagnostics, vaccines and pharmaceutical drugs.

<sup>7</sup> Klaus Stöhr and the WHO Multicentre Collaborative Network for SARS Diagnosis, 'A Multicentre Collaboration to Investigate the Cause of Severe Acute Respiratory Syndrome' (2003) 361 *The Lancet* 1730, 1731.

<sup>8</sup> Martin Enserink, 'Clues to the Animal Origins of SARS' (2003) 300 *Science* 1351; Judy Skatsoo, 'Civet Cats not the Original Source of SARS', *ABC Science News*, 5 October 2004 <<http://www.abc.net.au/science/news/stories/s1213117.htm>> at 5 October 2004. The civet cat is a species of the mongoose family (family *Viverridae*) found in Africa and Asia.

<sup>9</sup> Justin Gillis and Michael Barbaro, 'SARS No Boon for Drug, Biotech Firms', *The Washington Post* (Washington DC, USA), 17 April 2003, E01; Brian McGee, 'Hong Kong, Canada, US Scientists File SARS Patents, WSJ Says', *Bloomberg Newsfeed*, 5 May 2003.

<sup>10</sup> For an introduction to patent law, practice, and policy in the field of genetics, see Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, Report No 99 (2004).

<sup>11</sup> See, eg, Joseph Zeira, *Innovations, Patent Races and Endogenous Growth* (2003) Yale Department of Economics <<http://www.econ.yale.edu/seminars/macro/mac03/zeira-030304.pdf>> at 1 October 2004.

Second, the business managers of research institutions reluctantly relied upon the patent system to engage in technology transfer and protect public access to scientific research. Third, academics such as Richard Gold<sup>12</sup> and Peter Yu<sup>13</sup> argued that the race to patent the SARS virus revealed the need to reform the patent system. Finally, a number of idealists, such as Dr Marco Marra,<sup>14</sup> Margaret Atwood,<sup>15</sup> and Jeremy Rifkin,<sup>16</sup> expressed per se objections to the patenting of the genetic code of the SARS virus. Such complaints were grounded in ethical concerns about the commercialisation of scientific discoveries.

In charting this debate over gene patenting and the SARS virus, this article unashamedly favours a reformist approach. It contends that there is a need to modernise patent law to better reflect the large scale and collaborative nature of scientific projects — such as the international network of research into the SARS virus. First, this article considers the race between Canadian, Hong Kong, and US government researchers, and biotechnology companies to patent the genetic sequence of the SARS virus. It critically evaluates the claims of public laboratories that they are engaged in ‘defensive patenting’ to secure public access to scientific information. It argues that public research institutions should be given greater incentive and encouragement to cooperate and share research, rather than being driven to engage in patenting of research in light of the *Bayh-Dole Act* (US).<sup>17</sup> Second, this article considers the examination by the United States Patent and Trade Mark Office (‘USPTO’) of the patent applications in respect of the SARS virus and diagnostics. It evaluates the relevance of particular patent criteria in the US — such as patentable subject matter, novelty, inventive step, utility and secret use. It contends that there is a need to recalibrate such basic doctrinal concepts to better accommodate ‘Big Science’<sup>18</sup> projects. Third, this article considers the dispute over patent law and access to essential medicines. It evaluates whether the *Agreement on Trade-Related Aspects of Intellectual Property Rights*<sup>19</sup> and the *Doha Declaration on the TRIPS Agreement and Public Health*<sup>20</sup> are robust enough to deal with the emergence of new infectious diseases — such as the SARS virus. It

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<sup>12</sup> See E Richard Gold, ‘SARS Genome Patent: Symptom or Disease?’ (2003) 361 *The Lancet* 2002.

<sup>13</sup> See Peter Yu, ‘SARS and the Patent Race: An Introduction to the “Patent Law, Social Policy, and Public Interest” Symposium’ (2004) 22 *Cardozo Arts and Entertainment Law Journal*, available at <<http://ssrn.com/abstract=451640>> at 1 October 2004.

<sup>14</sup> Dirk Meissner, ‘SARS Gene Patent Application will Help Cure Research, Says BC Cancer Agency’, *The Canadian Press Newsfeed*, 5 May 2003 <<http://cmbi.bjmu.edu.cn/news/0305/71.htm>> at 1 October 2004.

<sup>15</sup> Sylvain-Jacques Desjardins, ‘Margaret Atwood: Back to the Future’ (2003) 35(15) *McGill Reporter* <<http://www.mcgill.ca/reporter/35/15/atwood>> at 1 October 2004.

<sup>16</sup> Paul Elias, ‘Government, Companies Race to Patent SARS Virus, Raising Ethics Questions’, *Associated Press Newsfeed*, 6 May 2003.

<sup>17</sup> *Bayh-Dole Act of 1980*, 35 USC §§ 200–12 (2002).

<sup>18</sup> ‘Big Science’ is a term used by historians of science to refer to large-scale scientific projects, which require massive government and industrial investment. World War II provided an important impetus for such endeavours as the Manhattan Project. The field of biology has featured ‘Big Science’ projects — such as the human genome project. Peter Galison and Bruce Hevly, *Big Science: The Growth of Large-Scale Research* (1992).

<sup>19</sup> *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995), annex 1C (*Agreement on Trade-Related Aspects of Intellectual Property Rights*) (‘TRIPS Agreement’).

<sup>20</sup> WTO Doc WT/MIN (01)/DEC/2 (2001).

focuses upon the institutional role of international organisations such as the World Trade Organization and the WHO. There is a need to ensure that the patent system is sufficiently flexible and adaptable to accommodate international research efforts on infectious diseases.

## II DUE PREPARATIONS FOR THE PLAGUE: THE DILEMMA OF DEFENSIVE PATENTS

The race to patent the SARS virus highlights the wider trend of public institutions increasingly relying upon patents in the field of biotechnology. In the US, the *Bayh-Dole Act* has encouraged universities to patent publicly funded research inventions.<sup>21</sup> Rebecca Eisenberg and Arti Rai observe:

The patenting trend accelerated significantly, however, after the passage of the *Bayh-Dole Act* in 1980. By 1997, the total number of patents issued annually to universities had increased to 2436. This almost ten-fold increase in university patenting was significantly greater than the two-fold increase in overall patenting during the same time period, and substantially exceeded growth in university research spending.<sup>22</sup>

The research institutions involved in SARS research were not only encouraged to file patents by this funding environment, but they were also driven by the need to preserve public access to the genetic material.

Three public research organisations — the BCCA, the CDC, and HKU — filed patents in respect of the genetic sequence of the SARS virus. The research institutions contended that it was necessary to engage in ‘defensive patenting’ to protect public access to scientific research. That is, by filing patent applications, they intended to pre-empt commercial applicants from obtaining patent rights that might hinder further research and development on SARS. Such a tactic is common amongst commercial firms. Kimberly Moore comments:

Defensive patenting often exists in a crowded art to provide the party with a repertoire of patents to use defensively as counterclaim weapons. These patents are used to strengthen a firm’s negotiating position with competitors (eg, as in cross-licensing). These patents may never be asserted affirmatively, but are maintained for defensive purposes when the patentee is threatened by competitors in a related field. It may be that foreign inventors acquire US patents for these defensive and signaling reasons to gain bargaining power in negotiations with competitors who threaten litigation.<sup>23</sup>

Such a strategy is not unprecedented in public universities or research institutions. Most notably, Michael Stratton and Cancer Research UK successfully sought a defensive patent in the European Patent Office in respect of research associated with the breast cancer-related gene, BRCA2.<sup>24</sup> Such a measure was designed to prevent rival Myriad Genetics from engaging in the exclusive licensing of genetic tests for BRCA2. It is worthwhile evaluating

<sup>21</sup> Arti Rai and Rebecca Eisenberg, ‘*Bayh-Dole Reform and the Progress of Biomedicine*’ (2003) 66 *Law and Contemporary Problems* 289, 292.

<sup>22</sup> Ibid.

<sup>23</sup> Kimberly Moore, ‘Xenophobia in American Courts’ (2003) 97 *Northwestern University Law Review* 1497, 1533.

<sup>24</sup> Susan Mayor, ‘Charity Wins BRCA2 Patent’, *The Scientist*, 13 February 2004 <<http://www.biomedcentral.com/news/20040213/02>> at 1 October 2004.

whether this strategy of 'defensive patenting' will be an effective and sustainable one in the context of research into the SARS virus.

Sceptics have pointed out that the term 'defensive patenting' has a double meaning. They intimate that the phrase is not just used to refer to the filing of patent applications in order to promote the greater public good. The term 'defensive patenting' is also employed where applicants acquire patents in order to prevent and block others from using them. In such circumstances, the motivation is a negative one, to restrict a rival's freedom to operate. Stuart MacDonald observes: 'A whole vocabulary has developed to describe the role of patents in corporate strategy; amidst patent clustering, patent bracketing, patent walling and patent blitzkrieg there may be little place for innovation'.<sup>25</sup> Such sceptics have highlighted the tensions inherent in the term, 'defensive patenting', between commercial imperatives and the public interest. They contend that scientists and university administrators intend to profit from the patents — rather than dedicate such inventions to the public domain. It is worth considering whether such cynicism is warranted in relation to the conduct of the research organisations involved in the SARS research.

#### A British Columbia Cancer Agency

At 4am, 12 April 2003, scientists at the Genome Sciences Centre of the BCCA completed the first publicly available draft sequence for a coronavirus implicated in SARS.<sup>26</sup> The SARS research involved collaboration with a number of other institutions — including the National Microbiology Laboratory in Winnipeg, the British Columbia Centre for Disease Control and University of British Columbia Centre for Disease Control, and the Department of Biochemistry and Microbiology at the University of Victoria.

In the prestigious journal *Science*, Dr Marco Marra and his various collaborators summarised their research into the SARS virus: 'We sequenced the 29 751 base genome of the severe acute respiratory syndrome (SARS) — associated coronavirus known as the Tor2 isolate'.<sup>27</sup> In the conclusion, the authors stressed the importance of this work from a public health perspective. In the short-term, they said, 'it will allow the rapid development of PCR-based assays for this virus that capitalize on novel sequence features, enabling ... discrimination between this and other circulating coronaviruses'.<sup>28</sup> The authors predicted: 'In the longer term, this information will assist in the development of antiviral treatments, including neutralizing antibodies and development of a vaccine to treat this emerging and deadly disease'.<sup>29</sup>

The BCCA filed a provisional patent application in the US claiming the complete genetic sequence of the coronavirus. It included details of the virus'

<sup>25</sup> Stuart Macdonald, 'Bearing the Burden: Small Firms and the Patent System' (2003) 1 *Journal of Information Law and Technology* [1.9.1] <<http://elj.warwick.ac.uk/jilt/03-1/macdonald.htm>> at 1 October 2004.

<sup>26</sup> BCCA, 'Genome Sciences Centre Sequences SARS Associated Corona Virus' (Press Release, 12 April 2003) <<http://www.bccancer.bc.ca/ABCCA/NewsCentre/2003/GenomeSciencesCentrecrackstheSARSvirusgenome.htm>> at 1 October 2004.

<sup>27</sup> Marco Marra et al, 'The Genome Sequence of the SARS-Associated Coronavirus' (2003) 300 *Science* 1399, 1399.

<sup>28</sup> Ibid 1403.

<sup>29</sup> Ibid.

genes, scientific analysis and general description of how the knowledge would be converted into diagnostics and treatments. The BCCA retained Smart & Biggar Fetherstonhaugh, a Vancouver law firm, to help prepare its case in patent law.<sup>30</sup>

The director of the BCCA Technology Development Office, Dr Samuel Abraham, was in charge of the patenting of the SARS virus. He applied the comprehensive patent and licensing policy of the BCCA.<sup>31</sup> The policy has very detailed guidelines dealing with collective authorship and collaboration with other institutions. The purpose of the policy is 'to encourage public use and commercial application of the research and development carried out at the BCCA/BCCF [British Columbia Cancer Foundation] while protecting the rights of the inventor(s) and the BCCA/BCCF'.<sup>32</sup> It deals with such important matters as ownership, collaborative research, the distribution of royalties and the disclosure of information.

Abraham was concerned that commercial firms would seek to patent the SARS virus and engage in exclusive licensing — the BCCA had experienced difficulties in the past obtaining access to patented genetic tests for breast cancer and ovarian cancer.

The BCCA has previously expressed concern about gene patents — in particular, Myriad Genetics' patents for BRCA1 and BRCA2.<sup>33</sup> In 2001, Myriad Genetics threatened to sue the British Columbia Government if the Government continued to allow genetic testing for BRCA1 and BRCA2 in the BCCA laboratories.<sup>34</sup> The British Columbia Health Ministry advised the BCCA it could no longer pay for the tests. Dr Charmaine Kim-Sing, head of breast cancer prevention for the cancer agency, said:

It's a huge blow for us. The cost is prohibitive. There isn't anyone who can come up with that kind of money — \$3850 is a lot of money for a blood test ... Our hope is that the government will step in and challenge the patent — they're the only ones who can afford the lawsuit.<sup>35</sup>

In 2002, Simon Sutcliffe, the director of BCCA, said 200 of the tests were sent to the Ontario Provincial Government, which was willing to carry out clinical work in spite of the patent.<sup>36</sup> The agency used to do its own tests until the British Columbia Government ordered it to stop after legal threats by Myriad Genetics. In 2003, the British Columbia Government decided to resume genetic testing for women who may be predisposed to breast and ovarian cancer.<sup>37</sup>

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<sup>30</sup> Lyle Stafford, 'Race on to Realize Value of SARS Patent', *The Toronto Star* (Toronto, Canada), 17 May 2003, C01.

<sup>31</sup> BCCA, *Patent and Licensing Policy* (1994) <<http://www.bccancer.bc.ca/NR/rdonlyres/e2n2oftoggyb3lg3eweaf4xvnxybw7citt6aa6t6zgoawadjl6spsyargmbprtw5hbsk3j62yhquaf/BCCAPatentPolicy.pdf>> at 1 October 2004.

<sup>32</sup> *Ibid* 1.

<sup>33</sup> Matthew Rimmer, 'Myriad Genetics: Patent Law and Genetic Testing' (2003) 25 *European Intellectual Property Review* 20.

<sup>34</sup> Wendy McLellan, 'Cost Rules Out Cancer Test for Women in BC', *The Province* (Vancouver, Canada), 21 September 2001, available at <<http://lists.essential.org/pipermail/ip-health/2001-September/001917.html>> at 1 October 2004.

<sup>35</sup> *Ibid*.

<sup>36</sup> 'BC Government Yields to US Company's Patent on Breast Cancer Gene', *The Canadian Press Newsfeed*, 21 October 2002.

<sup>37</sup> Colin Hansen, 'British Columbia to Resume Testing on Women for Cancer Despite Threat of Lawsuit', *CanWest News Service*, 16 February 2003.



Elsewhere, there has been controversy over patents being enforced in respect of the Hepatitis C virus ('HCV').<sup>38</sup> Scientists from Chiron Corporation in the US cloned HCV in 1987 and identified its role in some forms of hepatitis. This was the first time that an infectious agent had been identified by molecular cloning techniques alone and it was a fundamental breakthrough in research into infectious diseases. Chiron Corporation has been granted over 100 patents related to HCV in over 20 countries.<sup>39</sup> It has successfully defended its broad patents against legal challenges and has enforced its patent rights against infringing companies. The case of Chiron Corporation and its patents over the HCV have attracted wider comment in policy reviews, such as the Nuffield Council on Bioethics.<sup>40</sup>

In light of such concerns about the exclusive licensing of gene patents, Abraham considered a number of options to ensure that there was scientific access to the genetic information of the SARS virus. He took the pragmatic position that the patent system would consider that the research findings into the SARS virus would be considered to be patentable inventions, rather than scientific discoveries.<sup>41</sup> It was therefore misguided to work on the presumption that the genetic research would not be considered to be patentable subject matter. Abraham was sceptical of the strategy of open publication without seeking patent rights.<sup>42</sup> He noted that the single nucleotide polymorphism and express sequence tag consortiums had mixed results — companies could still claim patent rights after adding value to publicly available information.<sup>43</sup>

As a result, Abraham concluded that defensive patenting was the best available means of protecting the research into the SARS virus: 'The filing is to ensure that it is available to all, as opposed to making any kind of effort to delimit its distribution'.<sup>44</sup> Abraham elaborated:

We're basically trying to pre-empt the nonsense that has gone on in the past ... Most research institutions and most scientists have a knee-jerk reaction when they hear a patent has been filed. They read it as someone trying to corner the market. We're making sure the market is not cornered.<sup>45</sup>

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<sup>38</sup> Jon Cohen, 'The Scientific Challenge of Hepatitis C' (1999) 285 *Science* 26, 28.

<sup>39</sup> See, eg, European Patent 0318216.

<sup>40</sup> Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (2002) 40–1 <<http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf>> at 1 October 2004; *Murex Diagnostics Australia Pty Ltd v Chiron Corporation and Ortho Diagnostic Systems Inc* (1995) 55 FCR 194.

<sup>41</sup> Interview with Dr Samuel Abraham, Director, British Columbia Cancer Agency (Telephone interview, 4 November 2003).

<sup>42</sup> Ibid.

<sup>43</sup> For a discussion of the SNP consortium, see William Cornish, Margaret Llewelyn and Michael Adcock, *Intellectual Property Rights and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector* (2003) <[http://www.phgu.org.uk/about\\_phgu/intellect\\_prop\\_rights.html](http://www.phgu.org.uk/about_phgu/intellect_prop_rights.html)> at 1 October 2004.

<sup>44</sup> Antonio Regalado, 'Scientists' Hunt for SARS Cure Turns to Competition for Patents', *The Wall Street Journal* (New York, US), 5 May 2003, A1.

<sup>45</sup> Peg Brickley, 'Preemptive SARS Patents: US and Canadian Agencies Say Patents Will Preserve Access', *The Scientist*, 9 May 2003 <<http://www.biomedcentral.com/news/2003/0509/02>> at 1 October 2004.

Abraham said the cancer agency has received numerous requests for the SARS information since the discovery.<sup>46</sup> He reiterated: 'The reason for doing this was basically to enable all and sundry to get access to the various clones and material generated from this effort'.<sup>47</sup> The BCCA will pursue a strategy of non-exclusive licensing if it is granted patent rights to the SARS virus. Abraham said: 'If you try to gouge, nobody will come up to bat. That's the way the game is played'.<sup>48</sup> He acknowledged, though, that this policy option was not necessarily ideal because there was a great deal of expense involved in filing patent applications.<sup>49</sup>

Dr Abraham acknowledged, however, that the agency might seek royalties and other payments to fund more scientific research within the province:

The royalties, were there to be any at some later date, would come back to basically foster further research here. That would be a goal of any office of our type. If the strategy is ill-conceived, we will drop it and there won't be a patent.<sup>50</sup>

Abraham said the initial plan was to ensure that 50 per cent of any money goes to the research facility and the remaining 50 per cent to the scientists. This division of royalties reflected the position that was stated in the patent and licensing policy of the BCCA.<sup>51</sup> Abraham doubted whether there would be a financial windfall: 'If you're hoping to make money off this, you shouldn't even bother getting started. We're simply doing this to make the research available to anyone'.<sup>52</sup> He said that others that would share in any potential profits would include the British Columbia government, Health Canada and the University of Victoria, each of which help fund the BCCA.<sup>53</sup>

The leader of the genetic sequencing project, Dr Marco Marra, was ambivalent about the patent application in respect of the SARS virus. Professionally, he supported the patent application on the pragmatic grounds that it protected the freedom to conduct further research in the field: 'I believe that the agency is acting in the best interests of the public in protecting access to the sequence information'.<sup>54</sup> Personally, Marra had idealistic objections to patents being granted at all in respect of genes and gene sequences. He requested that his name not be included on the patent application: 'This stems largely from a personal belief that DNA sequence is a discovery as opposed to an invention and should not be patentable'.<sup>55</sup> Marra said he planned to decline any of the 50 per cent of licensing revenues the agency normally allocates to inventors. He believed genes should not be subject to patents because they are not true inventions and because they are now so easily and quickly deciphered.

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<sup>46</sup> 'BC Cancer Agency Seeks Patent for SARS Gene', *The Canadian Press Newsfeed*, 6 May 2003 <[http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20030506/sars\\_gene\\_patent\\_030506/?s\\_name=>](http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20030506/sars_gene_patent_030506/?s_name=>) at 1 October 2004.

<sup>47</sup> Ibid.

<sup>48</sup> Stafford, above n 30.

<sup>49</sup> Interview with Dr Samuel Abraham, above n 41.

<sup>50</sup> Meissner, above n 14.

<sup>51</sup> BCCA, *Patent and Licensing Policy*, above n 31.

<sup>52</sup> Stafford, above n 30.

<sup>53</sup> Ibid.

<sup>54</sup> Meissner, above n 14.

<sup>55</sup> Ibid.

Some Canadian government organisations took a more enterprising approach to the commercial prospects of SARS research. Alan Bernstein, President of the Canadian Institutes of Health Research, believed that it would be reasonable if the researchers sought patents to obtain private profit and to promote public access to information. He said: 'Patenting per se is not a bad thing. One proper reason for patenting is to make sure it's freely available to everybody'.<sup>56</sup> Anie Perault, a Vice-President of Genome Canada, which provided funding to set up the BCCA genetic laboratory, supported patent applications being filed in respect of the SARS research: 'Overall we think researchers should protect their intellectual property. We do favour commercialization but we don't have a position on how far it should go'.<sup>57</sup> Stephen Owen, the Secretary of State for Western Economic Diversification, heralded the scientific work of the BCCA as a commercial boon. He told the Canadian Parliament that there were opportunities to develop both genetic tests and vaccines for the SARS virus: 'This is a potential commercial follow-through from a great innovative breakthrough in mapping the SARS virus'.<sup>58</sup>

### B *US Centers for Disease Control and Prevention*

The CDC was also engaged in research in the SARS virus. A team of 10 scientists, supported by technicians, took 12 days to grow cells taken from a throat culture taken from one of the SARS patients in *Vero* cells in order to reproduce the ribonucleic acid ('RNA') of the disease-causing coronavirus. The CDC announced on 14 April 2003 that it had sequenced the genome for the coronavirus believed to be responsible for the global SARS epidemic.<sup>59</sup> The CDC discussed the relationship of this research to their Canadian counterparts:

The CDC sequence is nearly identical to that determined by a Canadian laboratory late last week. The significant difference is that the CDC-determined sequence has 15 additional nucleotides, which provides the important beginning of the sequence, CDC scientists said ...

The new sequence has 29 727 nucleotides, which places it well within the typical RNA boundaries for coronaviruses. The CDC sequence was nearly identical to that determined by the BCCA ...

The nearly identical findings in the US and Canada are important because they were derived from different individuals who were infected in different countries. This suggests that the virus probably originated from a common source.<sup>60</sup>

Strikingly, the CDC suggests that there are subtle but significant differences between their research and the findings of the BCCA.<sup>61</sup> It remains unclear what,

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<sup>56</sup> Ibid.

<sup>57</sup> Ibid.

<sup>58</sup> *Evidence before the Standing Committee on Industry, Science and Technology*, 37<sup>th</sup> Canadian Parliament, 2<sup>nd</sup> Session (14 May 2003) (Stephen Owen, Secretary of State, Western Economic Diversification) <<http://www.parl.gc.ca/InfocomDoc/37/2/INST/Meetings/Evidence/INSTEV45-E.HTM>> at 1 October 2004.

<sup>59</sup> CDC, 'CDC Lab Sequences Genome of New Coronavirus' (Press Release, 14 April 2003) <<http://www.cdc.gov/od/oc/media/pressrel/r030414.htm>> at 1 October 2004.

<sup>60</sup> Ibid.

<sup>61</sup> Ibid.

if any, bearing the discovery of the additional nucleotides will have upon the evaluation of any patent claims made in respect of the SARS virus.

Paul Rota of the CDC and his collaborators published the research in a May edition of *Science*.<sup>62</sup> In sequencing the genome, CDC scientists collaborated with coronavirus experts at academic institutions and research institutions. The CDC worked with researchers from the Departments of Biochemistry and Biophysics at the University of California–San Francisco, the Department of Virology at Erasmus University in the Netherlands, and the Department of Virology at the Bernhard Nocht Institute for Tropical Medicine in Germany. Dr William Bellini, SARS laboratory team coordinator, praised such international teamwork: ‘This is an active, working community of scientific experts who have been contributing their knowledge and expertise throughout this investigation’.<sup>63</sup> Dr Julie Gerberding, CDC Director, stressed the significance of the sequencing of the genome: ‘Research laboratories can use this information to begin to target antiviral drugs, to form the basis for developing vaccines, and to develop diagnostic tests that can lead to early detection’.<sup>64</sup>

The CDC was guided by its policy statement on ‘Cooperative Research and Development Agreements and Intellectual Property Licensing’, which emphasises: ‘For the CDC investigator, this agency mission prescribes the exploration of ideas, the communication of ideas and information to colleagues, and a responsibility for the prompt and accurate publication of findings’.<sup>65</sup> Under this policy, research results are disseminated freely through publication in the scientific literature and presentations at public fora. The policy acknowledges: ‘Brief delays in this dissemination of research results may be permitted under a [Cooperative Research and Development Agreement] as necessary in order to file corresponding patent or other intellectual property applications’.<sup>66</sup>

Following this policy, the CDC has submitted a patent application on the SARS virus and its entire genetic content. Rather than trying to profit if such a patent were awarded, the CDC, like the BCCA, says its application is to prevent others from monopolising the field. Dr Julie Gerberding said:

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<sup>62</sup> Paul Rota et al, ‘Characterization of a Novel Coronavirus Associated with Severe Acute Respiratory Syndrome’ (2003) 300 *Science* 1394.

<sup>63</sup> Ibid.

<sup>64</sup> CDC, *CDC Lab Sequences Genome*, above n 59.

<sup>65</sup> CDC, *Public Health Service Centers For Disease Control And Prevention Policy Statement on Cooperative Research and Development Agreements and Intellectual Property Licensing* (2002) <<http://www.cdc.gov/od/ads/techtran/forms/cradaa.htm>> at 1 October 2004.

<sup>66</sup> Ibid.

Our highest priority in all of this was to get information about SARS and the SARS genome and the SARS coronavirus into the public domain as quickly as we possibly can.

That's why we published the genome on the Web site. The concern that the federal government is looking at right now is that we could be locked out of this opportunity to work with this virus if it's patented by someone else, and so by initiating steps to secure patent rights, we assure that we will be able to continue to make the virus and the products from the virus available in the public domain, and that we can continue to promote the rapid technological transfer of this biomedical information into tools and products that are useful to patients.

So from our standpoint, it's a protective measure to make sure that the access to the virus remains open for everyone.<sup>67</sup>

CDC spokesman Llewellyn Grant reiterated: 'The whole purpose of the patent is to prevent folks from controlling the technology. This is being done to give the industry and other researchers reasonable access to the samples'.<sup>68</sup>

The CDC was conscious of competition to patent the SARS virus. Director of the Technology Transfer Office at the CDC, Andrew Watkins, commented: 'We made a decision early on to seek whatever patent protection we could get as a defensive measure, but not to delay publication of findings'.<sup>69</sup> He observed that the CDC's application does not purport to cover vaccines, diagnostic tests or other technology related to SARS.<sup>70</sup>

Watkins said that the Canadian research seemed to be moving on the same course as the US group.<sup>71</sup> He predicted that the most likely outcome for the Canadian and US applications was a negotiated joint ownership that could include hundreds of 'inventors' from different countries. However, Watkins noted that the research undertaken by HKU was dissimilar: 'To the extent there might be a competition, I don't think our goals are the same'.<sup>72</sup> Watkins noted that the USPTO could have to determine patent priority and ownership between the various parties:

If we're all trying to claim the same invention, including Hong Kong, then there would be an interference procedure in which the patent office would determine who was the first to invent. It could be we'll wind up with a jointly owned single patent, and we have not done that analysis yet.<sup>73</sup>

Watkins acknowledged that the work undertaken by the CDC involved a collaboration between a number of researchers and institutions: 'Even if the CDC's application wins, the ultimate inventor list will be much longer than the

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<sup>67</sup> *US Disease Centers Report SARS Containment Methods Working: Travel Advisories Lowered for Singapore, Vietnam* (2003) US Department of State <<http://usinfo.state.gov/gi/Archive/2003/May/20-192113.html>> at 1 October 2004.

<sup>68</sup> Paul Elias, 'Race to Patent SARS Virus Renews Debate', *Associated Press Newsfeed*, 5 May 2003.

<sup>69</sup> Brickley, above n 45.

<sup>70</sup> *Ibid.*

<sup>71</sup> *Ibid.*

<sup>72</sup> *Ibid.*

<sup>73</sup> *Ibid.*

CDC'.<sup>74</sup> However, it should be recognised that priority is only awarded to the first to invent in the jurisdiction of the US. Everywhere else in the world, priority would be awarded to the first to file the patent application.

### C *The University of Hong Kong and Versitech Ltd*

At the same time as the teams in North America were engaging in genetic research on the SARS virus, Professor Malik Peiris of HKU and his collaborators identified the coronavirus as a possible cause of SARS.<sup>75</sup> The researchers reported that 'a virus belonging to the family Coronaviridae was isolated from the lung biopsy and nasopharyngeal aspirate of two SARS patients and other patients with SARS had a serological response to this virus'.<sup>76</sup> Peiris said that after his team discovered the virus, it sent samples to other scientists but no patent was immediately sought. He maintained that the Hong Kong team only sought a patent after it became apparent that others were seeking them too.<sup>77</sup>

Dr Frederick Leung conceded that the Canadian and US research organisations uploaded sequences onto the National Center for Biotechnology Information first. However, he maintained that five days after his team had uploaded their sequences, their rival's flaws began to emerge:

They had to issue corrections and filled in the deficient sequences on later days whereas we were right from the start. It is disappointing because I do believe we deserve the recognition of being first.

This is critical in science, not least because we had the most accurate reporting yet *Science* took our rival's paper because they said they were first.<sup>78</sup>

Leung was proud of the effort of HKU, given its relative size: 'There were 10 of us whereas the Canadian group would have had 50–60 people and the US team have over 300 working for them'.<sup>79</sup>

HKU's intellectual property and technology transfer unit, Versitech Ltd, filed for patents over the SARS virus with the USPTO.<sup>80</sup> Hailson Yu, deputy managing director of Versitech Ltd, said: 'It's very competitive, but we think we are the early bird'.<sup>81</sup> He commented that a patent application was filed to ensure that academic institutions would not be blocked from studying the virus. He emphasised the need for freedom to operate in this field: 'If we didn't patent, for example, if there is a third party, they file a similar patent, and then eventually if we have to pay a license fee to do the research and the work on that subject

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<sup>74</sup> Ibid.

<sup>75</sup> J S M Peiris et al, 'Coronavirus as a Possible Cause of Severe Acute Respiratory Syndrome' (2003) 361 *The Lancet* 1319.

<sup>76</sup> Ibid 1323.

<sup>77</sup> Elias, 'Government, Companies Race to Patent SARS Virus, Raising Ethics Questions', above n 16.

<sup>78</sup> Louis Chow (ed), 'A Race Against Time: Cracking the Genetic Code of SARS Coronavirus' (2003) 8(1) *The University of Hong Kong Medical Faculty News* 10 <[http://www.hku.hk/facmed/newsletter/pdf/sars\\_special\\_issue.pdf](http://www.hku.hk/facmed/newsletter/pdf/sars_special_issue.pdf)> at 1 October 2004.

<sup>79</sup> Ibid.

<sup>80</sup> For more about the technology transfer unit, see Versitech Limited <<http://www.versitech.hku.hk>> at 1 October 2004.

<sup>81</sup> Regalado, above n 44.

matter, I don't think it is reasonable and logical'.<sup>82</sup> Yu said that the University would charge modest license fees to corporations who want to manufacture products. He added that the University was negotiating agreements with commercial partners for a diagnostic test. Yu anticipated that there would be significant discounts for academic researchers: 'We can license it for \$1 or one penny, you know, to grant the right for them to do the research'.<sup>83</sup>

A *South China Morning Post* correspondent, Jake van der Kamp, demanded that HKU clarify its intentions with regard to its SARS research.<sup>84</sup> He asked the pointed question: 'Does the University of Hong Kong seek to make money from its research work on SARS or will it give the world the benefit of that work for free?'<sup>85</sup> The correspondent observed:

What we need here is a statement from HKU that any SARS patent it may win will be made available to others for no cost. It is all very well that it should use such a patent to demand formal recognition of its work but this is as far as it should go.<sup>86</sup>

The correspondent concluded that 'it would strike a jarring note nonetheless if the cost of any medication that might result from the HKU research were to be higher because it has to be paid patent fees'.<sup>87</sup>

North American commentators also voiced suspicions about the patents sought by HKU. An article by Richard Gold from McGill University in *The Lancet* inspired a curt response from Professor Lap-Chee Tsui, the Vice-Chancellor of HKU.<sup>88</sup> Tsui has very personal experience of some of the issues related to patent law and genetics from his involvement in the race to discover the location of cystic fibrosis.<sup>89</sup> In 1989, he received international acclaim when he identified along with Francis Collins the defective gene that causes cystic fibrosis, which was a major breakthrough in human genetics. Tsui was Geneticist-in-Chief and Head of the Genetics and Genomic Biology Program of the Research Institute, at the Hospital for Sick Children in Toronto. He was the President of the Human Genome Organisation in 1999 and 2000. During that time, the organisation released a number of policy papers on gene patenting and benefit-sharing.<sup>90</sup>

Tsui was puzzled as to why Gold had singled out HKU in his defence of the CDC and the BCCA. Specifically, the commentary by Gold argued that the patent option would provide the two institutions 'with more leverage in dealing with [HKU's] Versitech'.<sup>91</sup> Gold further argued that CDC and BCCA would 'use

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<sup>82</sup> Joanne Silberner (Reporter), National Public Radio, 'Research Lab Tries to Patent Virus Causing SARS', *All Things Considered*, 9 May 2003.

<sup>83</sup> Ibid.

<sup>84</sup> Jake van der Kamp, 'HKU Patent Chase Raises Profit Questions', *South China Morning Post* (Hong Kong, China), 9 May 2003, 18.

<sup>85</sup> Ibid.

<sup>86</sup> Ibid.

<sup>87</sup> Ibid.

<sup>88</sup> Lap-Chee Tsui, 'SARS Genome Patent: To Manage and to Share' (2003) 362 *The Lancet* 406.

<sup>89</sup> Leslie Roberts, 'The Race for the Cystic Fibrosis Gene' (1988) 240 *Science* 141, 142-4.

<sup>90</sup> Ethics Committee, Human Genome Organisation, *Statement on Benefit-Sharing* (2000) <<http://www.hugo-international.org/hugo/benefit.html>> at 1 October 2004.

<sup>91</sup> Gold, above n 12, 2002.

the patent system to serve the public good'.<sup>92</sup> Tsui responded:

I wish to make clear that HKU is a research-led institution, committed to the public cause of higher education and benefiting society. Versitech is a technology transfer company, established in accordance with good practices of international universities to handle HKU's intellectual properties. Neither HKU nor Versitech are profit-seeking organisations, and they both hold the same view as CDC and BCCA — namely, to serve the public. HKU is committed to sharing its research results with society; locally, regionally, and internationally. We will continue to build up our research strength, but we cannot hope to share the benefits of our newly found knowledge if we do not properly manage our intellectual property rights.<sup>93</sup>

Tsui obviously resented the suspicions that were being aired about the patents sought by HKU and Versitech. He thought that it was a self-evident truth that the research organisation was engaged in 'defensive patenting' for the public good.<sup>94</sup>

#### D *Summary*

Public research institutions in Canada, the US and Hong Kong have filed patent applications on the genetic information of the SARS virus. These organisations have argued that it has been necessary to file patents in order to protect public access to the scientific information and research. There is no reason to doubt the sincerity of the motivations of the research institutions. Nonetheless, it is worthwhile acknowledging the limitations of the strategy of 'defensive patenting'. Richard Gold from McGill University comments:

One could argue that the CDC's and BCCA's use of the patents actually demonstrates that the patent system is working well. What this argument ignores is that, as genomic patents increase in number, it will become prohibitively expensive for public organisations to afford not only the expense of patenting genomes and DNA sequences, but also the significant costs of entering into licences and administering those licences. Expecting non-profit organisations to obtain patents on all their genomic inventions is not a sustainable solution to maintaining an open and free public domain.<sup>95</sup>

However, there have also been concerns expressed that the public research institutions will seek to commercialise any patents granted on the SARS virus. It remains to be seen whether the public research organisations will collaborate with commercial companies in order to develop diagnostic tests, vaccines and pharmaceutical drugs.

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<sup>92</sup> Ibid.

<sup>93</sup> Tsui, above n 88, 405.

<sup>94</sup> Letter from Lap-Chee Tsui to Matthew Rimmer, 20 November 2003.

<sup>95</sup> Gold, above n 12, 2002.



A number of commercial companies have been interested in developing genetic tests, diagnostics, and vaccines for the SARS virus.<sup>96</sup> A number of provisional patents have been filed in respect of commercial products relating to the SARS virus. However, the commercial value of such research and accompanying patents remains uncertain. As one commentator notes:

If efforts to contain the germ prove unsuccessful or if it re-emerges seasonally much like flu, the market for tests and treatments ultimately could be huge. But if the impact of the virus wanes after the current outbreak, companies will have little incentive to pursue the market.<sup>97</sup>

Peter Pekos, Chief Executive Officer of Dalton Chemical Laboratories Inc, predicted that the pursuit by medical researchers to profit from studying the illness is likely to be both sluggish and expensive: 'It's a gamble and there's a long time between the patent filing and the potential commercial payoff. It's not for the faint of heart. Most of the time, you're lucky if you can offset your patent costs'.<sup>98</sup> Similarly, Boston patent attorney Thomas Saunders, observed: 'This is no more than an opportunity to buy lottery tickets'.<sup>99</sup> It will take at least a few years for the patents filed by commercial companies on diagnostics, vaccines and pharmaceutical drugs to be issued.

In response to such commercial ventures, Ohio Democrat Congressman Dennis Kucinich expressed his concerns about the race to patent the SARS virus:

Any eventual vaccine or cure for SARS should also remain in the public domain so access to affordable treatment is possible in the event of a public health emergency. If the patent were held in private hands, it could prevent cooperative efforts among scientists across the globe and complicate efforts to make treatments or vaccines available to the public at large.<sup>100</sup>

Kucinich proposed the introduction of legislation 'that would create a new network of government labs for the research, development and manufacture of pharmaceutical products and biologics'.<sup>101</sup> He envisioned that the government laboratories would perform both research and development for new therapies and cures, and form cooperative agreements with educational, research and private

<sup>96</sup> See generally, Eric Feters, 'Mukilteo Company Joins War on SARS: CombiMatrix's Molecules Could Lead to New Drugs', HeraldNet, 8 May 2003; Regalado, above n 44; Stafford, above n 48; Roche Diagnostics, 'Roche SARS Test Now Available' (Press Release, 15 July 2003) <[http://www.roche-diagnostics.com/press\\_lounge/press\\_releases/archive/2003\\_07\\_15.html](http://www.roche-diagnostics.com/press_lounge/press_releases/archive/2003_07_15.html)> at 1 October 2004; Jeremy Torr, 'Biotron Files SARS Therapeutic Patent', *Australian Biotechnology News*, 29 July 2003; Andrew Pollack, 'Company Says It Mapped Part of SARS Virus', *The New York Times* (New York, US), 30 July 2003, 2; Viragen Inc, 'Viragen Drug Proves Effective against SARS in Research Study: Data from Study Strengthens Patent Application' (Press Release, 4 September 2003) <<http://www.viragen.com/pressreleases/2003/virpr09042003.htm>> at 1 October 2004; Graeme Smith, 'SARS Vaccines Stockpiled', *Globe and Mail*, 2 December 2003, A10; ABC Radio, 'Medical Researchers Work on Developing SARS Vaccine', *PM*, (Sydney, Australia), 5 December 2003 <<http://www.abc.net.au/pm/content/2003/s1004595.htm>> at 1 October 2004; and Deborah Smith, 'Australians Develop New SARS Test with Improved SARS Test', *The Sydney Morning Herald* (Sydney, Australia), 3 January 2004, 7.

<sup>97</sup> Regalado, above n 44.

<sup>98</sup> Stafford, above n 30.

<sup>99</sup> Brickley, above n 45.

<sup>100</sup> Dennis Kucinich, 'The Case for Public Patents', *The Nation* (New York, US), 19 June 2003 <<http://www.thenation.com/doc.mhtml?i=20030707&s=kucinich>> at 1 October 2004.

<sup>101</sup> *Ibid.*

institutions. Kucinich observed that the US Congress should not be beholden to the commercial desires of large pharmaceutical companies: 'Now faced with global public-health threats like SARS, we must stop foolishly pandering to the pharmaceutical industry and demand balance'.<sup>102</sup> He supported the use of an open source system to facilitate access to scientific information and improve research and development: 'This will allow us to tap the collective genius of the world community of scientists'.<sup>103</sup>

### III DISCOVERIES OF NATURE: GENE PATENTS AND THE PUBLIC GOOD

An editorial in the journal *Nature* discussed the race to patent the SARS virus in the context of 'Gene Patents and the Public Good'.<sup>104</sup> The opinion piece commented: 'A race to claim patents on the SARS virus raises questions about the patent system's ability to cope with genomics'.<sup>105</sup> The editorial elaborated:

CDC director Julie Gerberding told reporters last week that, in private hands, a patent on the viral sequence might delay the development and refinement of tests and treatments for the contagious pneumonia that has already killed several hundred people. Gerberding's admission gives tacit acknowledgement to a growing concern among biomedical researchers that broad patents on genetic sequences may, in some cases, have a stifling effect on research and negative consequences for public health.<sup>106</sup>

In the past, there have been similar competitions in respect of genetic research. Notable examples of such rivalry include the isolation of human insulin and growth hormone,<sup>107</sup> the discovery of the familial genes for breast and ovarian cancers,<sup>108</sup> and characterisation of the structure of DNA.<sup>109</sup> There have been concerns that patents held by private companies could inhibit research, particularly with respect to the development of clinical applications such as genetic tests. Furthermore, governments have been worried that the patent system could undermine the delivery of health care.

The patents filed in respect of the SARS virus have rekindled debate over the patenting of genes and other life forms. As the editorial in *Nature* opines:

There are no clear-cut answers. But when pre-emptive patenting is necessary to ensure that rapid solutions are found to an important health problem, something seems to be out of balance. Policy-makers should investigate what checks and balances are necessary to ensure that the patent system continues to do its job of stimulating innovation for the public good.<sup>110</sup>

There have been a number of policy reports dealing with these concerns regarding gene patents and human health. In 2002, US Representative Lynn

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<sup>102</sup> Ibid.

<sup>103</sup> Ibid.

<sup>104</sup> Editorial, 'Gene Patents and the Public Good' (2003) 423 *Nature* 207.

<sup>105</sup> Ibid 207.

<sup>106</sup> Ibid.

<sup>107</sup> Sally Smith Hughes, 'Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974–1980' (2001) 92 *Isis* 541, 551.

<sup>108</sup> Kevin Davies and Michael White, *Breakthrough: The Quest to Isolate the Gene for Hereditary Breast Cancer* (1995).

<sup>109</sup> Robert Cook-Deegan, *The Gene Wars: Science, Politics, and the Human Genome* (1994).

<sup>110</sup> Editorial, 'Gene Patents and the Public Good', above n 104.

Rivers sponsored a Bill in Congress that would have allowed health care entities to perform genetic diagnostic tests without fear of patent-infringement lawsuits.<sup>111</sup> In the UK, the Nuffield Council on Bioethics recommended that in future, patents on genetic sequences should be the exception rather than the rule.<sup>112</sup> In Canada, a report issued by Ontario's Provincial Government, following its experience with BRCA1 and BRCA2, explored solutions such as a compulsory licensing scheme in which a public entity would determine who should have access to which gene patents, and even set licensing fees.<sup>113</sup> The Canadian Biotechnology Advisory Committee has investigated broader issues associated with the patenting of higher life forms and human biological material.<sup>114</sup> The Australian Law Reform Commission has also considered policy options with respect to gene patents and human health.<sup>115</sup>

There is a need to reform the patent system to address the global nature of scientific inquiry, the unique nature of genetic science, and the increasing pace of technological change. There is a need to reconsider the patent criteria of the scope of patentable subject matter, novelty and inventive step, utility, and secret use. First, there has been much debate about the expansion of patentable subject matter to include biotechnological inventions. Second, there have been international tensions over the priority of inventions: the US patent regime favours the first to invent, whereas other jurisdictions award priority to the first to file a patent application. There is a need to raise the threshold for novelty and inventive step — in line with the recommendations of the Federal Trade Commission. Fourth, the USPTO issued new examination guidelines on the requirement of utility. It is contended that there needs to be a further tightening of the requirement of utility. Finally, the collaboration between multiple institutions poses problems in terms of prior art and secret use. The legislative reforms proposed by the Cooperative Research and Technology Enhancement (CREATE) Act ('CREATE Act')<sup>116</sup> seek to remedy some of the problems that arise in respect of such collaborative ventures. There is a need for further international harmonisation in terms of patent law and practice.

### A Patentable Subject Matter

The debate over the race to patent the SARS virus took place against a background of wider discussions over the impact of gene patents on health care.

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<sup>111</sup> The Genomic Research and Diagnostic Accessibility Act, HR 3967, 107<sup>th</sup> Cong (2002); The Genomic Science and Technology Innovation Act, HR 3966, 107<sup>th</sup> Cong (2002); 148 *Congressional Record* E353 (Extension of Remarks, 2002) (Lynn Rivers, House Science Committee).

<sup>112</sup> Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (2002) 70–3 <[http://www.nuffieldbioethics.org/publications/pp\\_0000000014.asp](http://www.nuffieldbioethics.org/publications/pp_0000000014.asp)> at 1 October 2004.

<sup>113</sup> Ontario State Government, 'Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare' *Draft Report to the Provinces and the Territories* (2002) <[http://www.health.gov.on.ca/english/public/pub/ministry\\_reports/geneticsrep02/report\\_e.pdf](http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf)> at 1 October 2004.

<sup>114</sup> Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Human Biological Material: An Introduction to the Issues* (2002).

<sup>115</sup> Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health*, above n 10.

<sup>116</sup> Cooperative Research and Technology Enhancement (CREATE) Act, HR 2391, 108<sup>th</sup> Cong (2003).

Since a pivotal US Supreme Court ruling in 1980, the USPTO has awarded patents for living things, most notably individual human genes.<sup>117</sup> Peter Yu considers moves to patent the SARS virus in light of the debate over gene patents:

Since *Chakrabarty*, patents have been granted on a wide variety of bio-engineered products, including polyploid Pacific oysters and the famous Harvard mouse. The US biotechnology industry has flourished, and the US has become a world leader in genetic research. Today, naturally occurring life forms remain ineligible for patent protection (since they are not inventions 'made by the hand of man'). However, one could arguably patent any gene or life form that has been modified by biotechnology, including genetic engineering.<sup>118</sup>

The US jurisprudence on gene patents has been influential on a number of other jurisdictions. Graham Dutfield comments: 'It is surely not coincidental that the USA pioneered both the commercialization of biotechnology applications and the development of patent law to protect them'.<sup>119</sup>

Biotechnology companies and pharmaceutical drug manufacturers argued that the aim of allowing patents on genes and organisms was to encourage the commercial development of useful inventions.<sup>120</sup> For instance, Franz Humer, the CEO of F Hoffmann-La Roche AG, maintained that patent protection is essential in the fight against diseases:

Our role is to find new drugs, and intellectual property rights is a framework in which innovation and competition can thrive. Patents are essential to guarantee continued high-risk investment in R&D. SARS is the latest reminder that new threats can emerge at any time. Therefore, we must maintain continuous capacity for mounting a brisk and effective response. This responsibility lies with the pharmaceutical industry; without patent protection, there is no research.<sup>121</sup>

However, there has been some doubt whether commercial incentives have been necessary to foster investment in SARS vaccines and diagnostics. Dr Dianne Nicol, of the Centre for Law and Genetics at the University of Tasmania, argued that the public health need for SARS-related tests, medicines and vaccines was so great that the need for incentives in this case seemed 'questionable'.<sup>122</sup>

Reformers have argued that the race to patent the SARS virus reveals the need to ameliorate the patent system. Richard Gold argues that there is a need for governments to address 'an emerging crisis of confidence in the patent

<sup>117</sup> *Diamond v Chakrabarty*, 447 US 303 (1980).

<sup>118</sup> Peter Yu, 'SARS and the Patent Race: What Can We Learn from the HIV/AIDS Crisis?', *Find Law*, 29 May 2003 <[http://writ.news.findlaw.com/commentary/20030529\\_yu.html](http://writ.news.findlaw.com/commentary/20030529_yu.html)> at 1 October 2004.

<sup>119</sup> Graham Dutfield, *Intellectual Property Rights and the Life Science Industries* (2003) 154.

<sup>120</sup> See generally, Deborah Smith, 'Rush to Patent Virus and Genes', *The Sydney Morning Herald* (Sydney, Australia), 7 May 2003, 3; Dianne Nicol and Jane Nielsen, 'Patents and Medical Biotechnology: An Empirical Analysis of Issues Facing the Australian Industry' (Occasional Paper No 6, Centre for Law and Genetics, University of Tasmania, 2003) ch 3.

<sup>121</sup> Franz Humer, 'Fighting Epidemics: A Global Priority?' (Speech delivered at the 33<sup>rd</sup> International Students' Committee Symposium, 'Seeking Response in Times of Uncertainty', St Gallen, Switzerland, 23 May 2003) <[http://www.isc-symposium.org/ISC/abstract\\_Humer\\_und\\_Krebs.pdf](http://www.isc-symposium.org/ISC/abstract_Humer_und_Krebs.pdf)> at 1 October 2004.

<sup>122</sup> Smith, above n 120, 3.

system'.<sup>123</sup> He goes on to recommend a number of generic reforms to the patent system:

The drafting of licensing guidelines to ensure access to genomic developments, introducing compulsory licensing provisions, better defining the experimental use exception in countries without a clear exception (eg, the USA and Canada), and introducing a morality clause linked to the manner in which genomic and genetic inventions are commercialised. It is unlikely that that any one option will work alone. For example, industry will probably only follow licensing guidelines if governments make it clear that they are prepared to grant compulsory licences if these guidelines are not implemented.<sup>124</sup>

Gold suggests that the debate over the SARS virus highlights the need for the reform: 'The patent system needs to be adjusted — not discarded — by governments to better reach the goal of that system: the attainment of the public good'.<sup>125</sup>

By contrast, idealists have expressed per se objections to the patenting of the SARS virus. Some commentators maintain that patents should not be granted in respect of natural products. A long-time opponent of the patenting of biotechnological inventions, Jeremy Rifkin, argued in respect of SARS:

These are discoveries of nature and it's baloney that we allow patents on living things. We didn't allow chemists to patent the periodic table — there's no patent on hydrogen and I don't see why they can patent discoveries of nature.<sup>126</sup>

Many scientists argue that patents should not be issued for genes on the grounds that genes are scientific discoveries, not inventions.<sup>127</sup> For instance, Marco Marra of the BCCA believed that the SARS virus should not be the subject of a patent because it was a scientific discovery: 'This stems largely from a personal belief that DNA sequence is a discovery as opposed to an invention and should not be patentable'.<sup>128</sup>

Other critics argue that intellectual property rights and life forms are incompatible.<sup>129</sup> For instance, the novelist Margaret Atwood raised concerns about the commodification of life. Her latest book, *Oryx And Crake*, is a satire about the corruption of science by commerce.<sup>130</sup> Atwood was alarmed by the patents filed on the SARS virus:

A really good example of why you shouldn't commercialize everything is the SARS epidemic. If public health were something that had to be paid for by an individual, the thing would be all over the place by now. Our world is not made of watertight compartments. Choices will come along soon. We hope that we will make the informed ones. We hope that we will not commercialize bloody

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<sup>123</sup> Gold, above n 12, 2002.

<sup>124</sup> Ibid.

<sup>125</sup> Ibid.

<sup>126</sup> Elias, 'Government, Companies Race to Patent SARS Virus, Raising Ethics Questions', above n 16.

<sup>127</sup> David Resnik, 'Discoveries, Inventions And Gene Patents' in David Magnus, Arthur Caplan and Glenn McGee (eds), *Who Owns Life?* (2002) 135.

<sup>128</sup> Meissner, above n 14.

<sup>129</sup> Mark Hanson, 'Patenting Genes and Life: Improper Commodification' in Magnus, Caplan and McGee, above n 127, 161.

<sup>130</sup> Margaret Atwood, *Oryx and Crake* (2003).

everything. We hope that there will be watchdogs in place to keep things from getting out of hand.<sup>131</sup>

The USPTO is unconvinced by such per se objections to the patenting of life forms. It insists that ‘anything under the sun made by man’ is patentable subject matter — including, presumably, the SARS virus.<sup>132</sup> However, arguments that patents should not be granted on higher life forms may receive a more sympathetic hearing in Canada.<sup>133</sup>

### B Novelty and Inventive Step

Given that the three public research institutions — the BCCA, the CDC and Versitech — all filed patent applications in the USPTO, it is worthwhile considering US patent law and practice in some further detail.

Unlike most other jurisdictions, the USPTO awards patents to the first to invent, not the first to file an application for a patent. Peter Yu comments that it will be difficult to resolve complex disputes over priority in respect of treatments of the SARS virus.<sup>134</sup> He observes:

Although the patent race is heated, there likely will not be a clear winner — or there might be many winners. There are several reasons.

Under US law, a patent can be granted on a specific part of the SARS virus or on ‘improvements’ of what has already been discovered. Because the virus mutates from one form to another, the patent applicant might claim rights in only a specific mutation of the virus, rather than its original form or its other variants.

While the US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file the application. Because of these differences, the US and European patent holders theoretically could be different.<sup>135</sup>

It will be difficult to determine the priority of the patent applications in the complex set of international collaborations. The situation is further complicated by a lack of harmonisation of rules governing novelty and inventive step.

In matters where two or more inventors submit patent applications claiming the same invention, the USPTO engages in ‘interference’ proceedings to determine the first to invent.<sup>136</sup> In an empirical study of this unique system, Jon Merz and Michelle Henry found that interference proceedings in gene discovery and biotechnology are much more prevalent than in other areas of technology.<sup>137</sup> They consider a number of notable races for genetic discovery, and conclude:

<sup>131</sup> Desjardins, above n 15.

<sup>132</sup> USPTO, ‘Utility Examination Guidelines’ (2001) 66 *Federal Register* 1092 <<http://www.uspto.gov/web/offices/com/sol/notices/utilexmguid.pdf>> at 1 October 2004.

<sup>133</sup> In *Harvard College v Canada (Commissioner of Patents)* [2002] 4 SCR 45, 219 DLR (4<sup>th</sup>) 577, 643, the Supreme Court of Canada held, in a recent 5:4 decision, that higher life forms such as the oncomouse were not patentable subject matter.

<sup>134</sup> Yu, ‘SARS and the Patent Race: What Can We Learn’, above n 118.

<sup>135</sup> *Ibid.*

<sup>136</sup> USPTO, ‘Interference Proceedings’, *Manual of Patent Examining Procedure* (2004) <<http://www.uspto.gov/web/offices/pac/mpep/documents/2300.htm>> at 1 October 2004.

<sup>137</sup> Jon Merz and Michelle Henry, ‘The Prevalence of Patent Interferences in Gene Technology’ (2004) 22 *Nature Biotechnology* 153, 153.

The high level of competition in these cases suggests several things about the nature of the research. First, without taking any credit away from the scientists so engaged, gene discovery has become ordinary. Many share necessary intellectual know-how, and success is predicated upon the ability and luck in identifying, soliciting and studying the 'right' families and groups. Second, as in other scientific fields, these discoveries build upon knowledge contributed by others, reflecting the co-dependent, but competitive, environment of science.<sup>138</sup>

In further research, Mark Lemley and Colleen Chien comment: 'In over 40 per cent of the cases, the first to invent is last to file'.<sup>139</sup> Furthermore, 'a large number of priority disputes involve near-simultaneous invention; and that the vast majority of such disputes could be resolved without reliance on much of the evidence that the law permits'.<sup>140</sup> Such evidence raises questions whether this unique system is worth retaining as a means of determining priority.

To obtain patents over the SARS virus, the various applicants will have to demonstrate that their invention is 'novel' and distinguishable from the 'prior art' — materials and inventions that exist before the patent application. It will be difficult for the parties to sift through the prior art with respect to coronaviruses, and demonstrate that the invention is novel and inventive. An elementary search revealed that 618 patents filed in the USPTO mentioned the keyword 'coronavirus'.<sup>141</sup> Of those, 89 patents mentioned 'coronavirus' in the claims. Singapore patent attorney Aaradhana Sadasivam comments:

A wealth of published and granted patent applications are available on corona viruses — the close relative of the SARS virus, and of course vaccines, techniques, and methods of protection against it. Several patents have already been published and granted by major jurisdictions such as the USPTO, EPO and the International Bureau. Some examples include an application for a Canine coronavirus S gene and Uses Thereof (US6057436), Anti-Coronavirus vaccine (WO03013599), Methods for Producing Recombinant Coronavirus (WO02086068) and Canine Coronavirus Vaccines (IE881689L).<sup>142</sup>

Therefore it is necessary for patent applicants to engage in a thorough mapping of the existing field of patents and other prior art. A medical or scientific research effort would presumably need to analyse the pre-existing body of scientific data, tests and results in the same area of research. The use of such patented data would require the necessary consents and licences to be sought and obtained before using them legitimately for the purpose of commercialisation.

Some enterprising souls have sought to provide commercial assistance in charting the prior art. Ella Cheong, Miranda and Sprusons have been advertising a SARS Patent Mapping Report for the princely sum of US\$2950 (discounted from US\$5800).<sup>143</sup> The authors vaunt the report:

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<sup>138</sup> Ibid (citations omitted).

<sup>139</sup> Mark Lemley and Colleen Chien, 'Are the US Patent Priority Rules Really Necessary?' (2003) 54 *Hastings Law Journal* 1299, 1300.

<sup>140</sup> Ibid.

<sup>141</sup> *USPTO Patent Full-Text and Image Database*, USPTO, available from <<http://www.uspto.gov>> at 1 October 2004.

<sup>142</sup> Aaradhana Sadasivam, 'Patent System Central to a SARS Vaccine' (2003) 134 *Managing Intellectual Property* 29.

<sup>143</sup> Zuzy Hamid et al, 'SARS Patent Analysis and Mapping' (2<sup>nd</sup> ed, 2003) <<http://patentmaps.com/pubs/SARS>> at 1 October 2004.

The SARS Patent and Analysis Report presented a detailed analysis of the patent maps of virus and specifically coronavirus related technologies. There is a rich corpus of patent documents pertaining to molecular biology, and nearly 4000 are virus related to viral diagnostics and therapeutics.<sup>144</sup>

However, the Report merely provides a map of existing patents related to viruses. It does not yield any new insights into the patenting practices of research institutions and commercial companies in relation to the SARS virus.

In its report, *To Promote Innovation*, the Federal Trade Commission provides a number of creative reform proposals with respect to novelty and inventive step in the US.<sup>145</sup> It recommends that Congress tighten legal standards to determine whether an invention is 'obvious':

It is important to protect against the issuance of obvious patents that may confer market power and unjustifiably raise costs. Requiring concrete suggestions beyond those actually needed by a person with ordinary skill in the art, and failing to give weight to suggestions implicit from the art as a whole and from the nature of the problem to be solved, is likely to result in patents on obvious inventions and is likely to be unnecessarily detrimental to competition. The Federal Circuit's most recent articulations of the suggestion test seem to signal greater appreciation of these issues and would better facilitate implementation of the test in ways sensitive to competitive concerns.<sup>146</sup>

The Federal Trade Commission urges that in assessing obviousness, the analysis should ascribe to the person having ordinary skill in the art an ability to combine or modify prior art references that are consistent with the creativity and problem-solving skills that in fact are characteristic of those having ordinary skill in the art. It argues that failing to give weight to suggestions implicit from the prior art as a whole, suggestions from the nature of the problem to be solved, and the ability and knowledge of one of ordinary skill in the art, errs on the side of issuing patents on obvious inventions and is likely to be unnecessarily detrimental to competition.

There are other mechanisms available to resolve the disputes over priority. Dr Samuel Abraham of the BCCA has suggested that patent pooling might be one possible solution to resolve the competing claims for patents in respect of the SARS virus.<sup>147</sup>

Members of the USPTO have published a paper on whether patent pools are a solution to the problem of access in respect of biotechnology patents.<sup>148</sup> They define a 'patent pool' as an 'agreement between two or more patent owners to license one or more of their patents to one another or third parties'.<sup>149</sup> Alternatively, a patent pool may also be defined as 'the aggregation of intellectual property rights which are the subject of cross-licensing, whether they

<sup>144</sup> Zuzy Hamid, *Pre-licensing Consideration through Patent Mapping* (2003) <<http://patentmaps.com/pubs/2003Oct06zya.pdf>> at 1 October 2004.

<sup>145</sup> Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) <<http://www.ftc.gov/os/2003/10/innovationrpt.pdf>> at 1 October 2004.

<sup>146</sup> Ibid 15.

<sup>147</sup> Interview with Dr Samuel Abraham, above n 41.

<sup>148</sup> Jeanne Clark et al, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents* (2000) <<http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf>> at 1 October 2004.

<sup>149</sup> Ibid 3.



are transferred directly by patentee to licensee or through some medium, such as a joint venture, set up specifically to administer the patent pool'.<sup>150</sup> The USPTO paper is optimistic about the use of patent pools to solve access problems: 'The use of patent pools in the biotechnology field could serve the interests of both the public and private industry, a win-win situation'.<sup>151</sup>

Such proposals have been met with mixed responses. David Resnik is a champion of such a scheme: 'Industry leaders and scientists could choose the path of enlightened self-interest by forming a biotechnology patent pool'.<sup>152</sup> However, Lori Andrews raises serious concerns about whether patent pools are particularly well adapted to gene patents: 'Gene patent holders may be less likely to participate in voluntary patent pools than are patent holders from other industries'.<sup>153</sup> The Organisation for Economic Co-operation and Development has echoed such complaints:

It is true that there is a growing interdependence among patents, that the claims of many patents are narrower, and that patents are held by multiple owners. Licensing transaction costs are burdensome and freedom of operation is restricted, thus increasing the potential for conflict among researchers. However, the pharmaceutical biotechnology industry may be fundamentally different from the electronics sector. It is not an industry in which defining standards is important, and assuring interoperability of technologies is not very important, especially not in the development of therapeutics. A company's worth is tightly tied to its intellectual property and fosters a 'bunker mentality'.<sup>154</sup>

Furthermore, there is ongoing debate about whether patent pools have anti-competitive effects in the marketplace. It has been noted that patent pools could in some circumstances encourage collusion and price fixing, and raise the costs of technologies.<sup>155</sup>

### C Utility

In the debate over the race to patent the SARS virus, John Doll, the director of biotechnology for the USPTO, affirmed that a patent would need to satisfy the requirement of utility: 'It must have a real world utility and there has to be the hand of man involved. You can't just turn over a rock and scrape something off the bottom of it and apply for a patent'.<sup>156</sup>

In the US, the courts have sought to define the requirement of utility under patent law. In *Brenner v Manson*, the US Supreme Court took a restrictive view of utility.<sup>157</sup> It held that a chemical product with no known use, or useful for

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<sup>150</sup> Ibid.

<sup>151</sup> Ibid 11.

<sup>152</sup> David Resnik, 'A Biotechnology Patent Pool: An Idea Whose Time Has Come?' (2003) 3 *Journal of Philosophy, Science and Law* [9] <<http://www.psljournal.com/archives/papers/biotechpatent.cfm>> at 1 October 2004.

<sup>153</sup> Lori Andrews, 'The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs' (2002) 2 *Houston Journal of Health Law and Policy* 65, 102.

<sup>154</sup> OECD, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* (2002) 67.

<sup>155</sup> Clark et al, above n 148, 11–12.

<sup>156</sup> Elias, 'Government, Companies Race to Patent SARS Virus, Raising Ethics Questions', above n 16.

<sup>157</sup> *Brenner v Manson*, 383 US 519 (1966).

merely further research, was not a patentable invention. Justice Fortas emphasised the importance of the requirement of utility in patent law: 'The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility'.<sup>158</sup> Emphasising that 'a patent is not a hunting license', his Honour concluded: 'It is not a reward for the search, but compensation for its successful conclusion'.<sup>159</sup>

In 2001, the USPTO issued revised examination guidelines explaining how the utility requirement should be applied by patent examiners.<sup>160</sup> The guidelines required patent applicants to explicitly identify, unless already well established, a specific, substantial and credible utility for all inventions. In effect, it raised the bar to ensure that patent applicants demonstrate a 'real world' utility. Todd Dickinson explained the administrative reforms to Congress.<sup>161</sup> He observed: 'An asserted utility is credible unless the logic underlying the assertion is seriously flawed, or the facts upon which the assertion is based are inconsistent with the logic underlying the assertion'.<sup>162</sup> Dickinson noted: 'A utility is specific when it is particular to the subject matter claimed'.<sup>163</sup> Finally, he observed: 'A substantial utility is one that defines a "real world" use'.<sup>164</sup>

There has been much discussion about the new USPTO examination guidelines for the requirement of utility.<sup>165</sup> The Nuffield Council on Bioethics has argued that the USPTO has set the requirement of utility too low:

While we welcome the new USPTO guidelines, we take the view that where 'credibility' means no more than 'theoretical possibility' (ie where something is credible simply where it is not incredible) the threshold for utility is still set too low. The current state of genetics and biochemistry does not make it difficult to suggest functions for DNA sequences that are 'theoretically possible', in the sense that they are not ruled out by what is already known; but this should not suffice for the award of a patent. Instead, what is required is some evidence that the DNA sequence actually has the claimed 'specific' utility and that the claimed utility is truly 'substantial'.<sup>166</sup>

The Council recommended that the USPTO should monitor the impact of the Guidelines on the examination of patents to ensure that the criterion for utility was rigorously applied so that the grant of a patent more properly reflects the

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<sup>158</sup> Ibid 534.

<sup>159</sup> Ibid 536.

<sup>160</sup> USPTO, 'Utility Examination Guidelines', above n 132.

<sup>161</sup> *Statement of Todd Dickinson Before the Subcommittee on Courts and Intellectual Property of the House Committee on the Judiciary*, 13 July 2000 (Todd Dickinson, Under Secretary of Commerce for Intellectual Property and Director of the USPTO) <<http://www.house.gov/judiciary/dick0713.htm>> at 1 October 2004.

<sup>162</sup> Ibid.

<sup>163</sup> Ibid.

<sup>164</sup> Ibid.

<sup>165</sup> Joshua Benson, 'Resuscitating the Patent Utility Requirement, Again: A Return to *Brenner v Manson*' (2002) 36 *University of California Davis Law Review* 267; Mary Breen Smith, 'An End to Gene Patents? The Human Genome Project Versus the United States Patent and Trademark Office's 1999 Utility Guidelines' (2002) 73 *University of Colorado Law Review* 747; Tanya Wei, 'Patenting Genomic Technology — 2001 Utility Examination Guidelines: An Incomplete Remedy in Need of Prompt Reform' (2003) 44 *Santa Clara Law Review* 307.

<sup>166</sup> Nuffield Council on Bioethics, above n 112, 45.

inventor's contribution. If this proves not to be the case, the Guidelines should be reviewed and strengthened to achieve this purpose as soon as is practicable.<sup>167</sup>

Against this background, the USPTO will have to determine whether the patents filed in respect of the genetic sequence of the SARS virus have a specific, substantial and credible utility. The examiners will also have to be mindful of the requirement of utility in dealing with downstream inventions — such as genetic tests, vaccines and pharmaceutical drugs. In particular, care must be taken to ensure that patents are not granted to spurious cures for the SARS virus.<sup>168</sup> There is a need for examiners to subject patent applications to close scrutiny.

#### D *Secret Use and the Grace Period*

Some commentators have speculated that the sharing of information about SARS research among the network of research institutions could affect the validity of at least some of the applications and the entitlement to some patent rights.<sup>169</sup> There have been doubts as to whether a grace period is an effective means of dealing with such issues.<sup>170</sup>

In the wake of the quest for the sequence of the SARS virus, Representative Lamar Smith of the 21<sup>st</sup> District of Texas put forward the CREATE Act.<sup>171</sup> Smith is the Chairman of the influential Subcommittee on Courts, the Internet, and Intellectual Property. Representative Smith argued that the patent system should be amended to recognise the collaborative nature of research across multiple institutions. He cited the case of SARS research as a primary example of collaborative research that takes place across public and private institutions:

Congress should act to promote innovation and communication among researchers, and streamline patent application approval. The success scientists achieved in rapidly identifying the cause of severe acute respiratory syndrome (SARS) is a recent example of how collaboration among government and private labs can save lives and protect the public. The reaction to the SARS virus demonstrates that in an increasingly connected world, it is necessary for our public and private organizations to adapt to new challenges and develop new ways of doing business.<sup>172</sup>

Understanding the need to facilitate collaboration within institutions, Congress had earlier enacted a series of amendments to patent law in 1984, with the *Patent Law Amendments Act*.<sup>173</sup> Section 103(c) created a 'safe harbor' for

<sup>167</sup> Ibid 60.

<sup>168</sup> Judi Gatson (Reporter), 'Buyer Beware: Phony SARS Cures', *WIS News 10* (Columbia, US), 10 June 2003 <<http://www.wistv.com/Global/story.asp?s=%20%201315569>> at 1 October 2004.

<sup>169</sup> James Cherry and Tom Gumley, 'Patenting SARS — A Novel Idea?' (2003) 16 *Australian Intellectual Property Law Bulletin* 17.

<sup>170</sup> Ann Monotti, 'The Impact of the New Grace Period under Australian Patent Law on Universities' (2002) 24 *European Intellectual Property Review* 475.

<sup>171</sup> Cooperative Research and Technology Enhancement (CREATE) Act, HR 2391, 108<sup>th</sup> Cong (2003).

<sup>172</sup> Lamar Smith, *Rep Smith's Remarks to the American Intellectual Property Law Association (AIPLA)* (2003) <<http://lamarsmith.house.gov/tech.asp?id=331>> at 1 October 2004.

<sup>173</sup> *Patent Law Amendments Act of 1984*, Pub L No 98-622, 98 Stat 3383 (codified as amended in scattered sections of 35 USC).

inventions that were the product of a collaboration involving co-inventors within a single company.<sup>174</sup> In *OddzOn Products Inc v Just Toys Inc*, the US Court of Appeals for the Federal Circuit narrowly interpreted § 103(c) of Title 35, USC.<sup>175</sup> Somewhat apologetically, the Court of Appeals held that the amendment allowed for the disclosure of information among collaborators within the same organisation, but did not extend to the sharing of information within multiple institutions:

It is historically very clear that this provision was intended to avoid the invalidation of patents under § 103 on the basis of the work of fellow employees engaged in team research. There was no clearly apparent purpose in Congress's inclusion of § 102(f) in the amendment other than an attempt to ameliorate the problems of patenting the results of team research.<sup>176</sup>

The decision created a threat that a patent could be invalidated in the circumstances of a collaborative research effort involving multiple organisations.

The CREATE Act sought to expand the secret prior art exception to collaborators involving 'team researchers' located at multiple organisations. The amendments dealt with the limitation on non-public information in obviousness determinations. Section 2 proposed amending § 103(c) of Title 35, USC to ensure that prior art should not preclude patentability where the subject matter and the claimed invention were owned by the same person or subject to an obligation of assignment to the same person. It defined the term 'joint research agreement' as meaning 'a written contract, grant, or cooperative agreement entered into by two or more persons or entities for the performance of experimental, developmental, or research work in the field of the claimed invention'. Under § 3, the amendments shall apply to any patent granted on, or after the date of the Act's enactment. The amendments made by this Act would not affect any final decision of a court or the USPTO that was rendered before the date of enactment, nor affect the right of any party in any action pending before the USPTO or a court. It is uncertain whether such legislation, if enacted, would apply to the collaborators in the SARS research network. Much will depend upon the dates at which patents dealing with the SARS virus are granted.

The House of Representatives Subcommittee on Courts, the Internet and Intellectual Property conducted an oversight hearing on the topic.<sup>177</sup> A number of witnesses gave evidence relating to the intersection of patent law, cooperative research, technology transfer and biotechnology issues. Jon Soderstrom, the head of the Office of Cooperative Research at Yale University, observed:

The evolution of science has made interdisciplinary research more and more common and, in fact, essential if solutions to complex problems are to be found. The recent stunning example of SARS is but one of many.<sup>178</sup>

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<sup>174</sup> *Patent Law Amendments Act of 1984* § 103, 35 USC § 103(c) (2002).

<sup>175</sup> *OddzOn Products Inc v Just Toys Inc*, 122 F 3d 1396 (1997).

<sup>176</sup> *Ibid* 1403.

<sup>177</sup> *Cooperative Research and Technology Enhancement (CREATE) Act of 2003: Hearing on HR 2391 before the Subcommittee on Courts, the Internet, and Intellectual Property of the House Committee on the Judiciary*, 108<sup>th</sup> Cong, 1<sup>st</sup> Sess (2003) <<http://www.house.gov/judiciary/87624.PDF>> at 1 October 2004.

<sup>178</sup> *Ibid* 5.

The Senate approved the CREATE Act on 25 June 2004. Senator Orrin Hatch commented: 'This act will encourage greater cooperation among universities, public research institutions and the private sector'.<sup>179</sup> It remains uncertain whether the legislation will be passed because of the Presidential election.

### E Summary

The international research into the SARS virus is characteristic of 'Big Science' projects, which have become a feature of modern genomics. Such enterprises are characterised by international collaborations between a range of institutions and multiple authors.<sup>180</sup> The patent system is ill-adapted to deal with global research initiatives, which involve multiple researchers and institutions across a number of countries. In an article entitled 'An International Patent Utopia?', Paul Edward Geller comments:

The old patent regime has fallen out of step with technological progress. Mankind started with trial-and-error tinkering and shifted to cumulative experimentation. In modern times, applied science has helped to industrialise research and development. Paradoxically, as this progress has accelerated, it has precipitated the patent crisis. Ever-increasing numbers of ever-more complex filings are swamping patent offices. The old regime has not kept pace on critical points: efficiency and transparency.<sup>181</sup>

There is a need for a systematic revision of the patent system, so that it reflects the collaborative, international character of large-scale research projects. Such patent criteria as novelty, inventive step, utility, and secret use should be recalibrated in light of the global nature of scientific inquiry in the field of genetics.

## IV VIRAL NETWORKS: THE *TRIPS* AGREEMENT AND ACCESS TO ESSENTIAL MEDICINES

The race to patent the SARS virus has raised wider issues about patent law and access to essential medicines. There has been much discussion in international forums such as the WTO and the WHO about the circumstances in which national governments can invoke compulsory licensing provisions in public health epidemics and other national emergencies. Concerns have been raised about access to essential medicines in the context of disputes over AIDS drugs.<sup>182</sup> There has been intense debate between stakeholders — patent holders in respect of pharmaceutical drugs and vaccines have been pitted against developing countries, generic drug manufacturers, and human rights and aid

<sup>179</sup> 150 *Congressional Record* S7520 (2004) (Senator Hatch, Chairman of the Senate Judiciary Committee).

<sup>180</sup> See generally Peter Galison, 'The Many Faces of Big Science' in Peter Galison and Bruce Hevly (eds), *Big Science: The Growth of Large-Scale Research* (1992); Mario Biagioli, 'Rights or Rewards? Changing Frameworks of Scientific Authorship' in Mario Biagioli and Peter Galison (eds), *Scientific Authorship: Credit and Intellectual Property in Science* (2003).

<sup>181</sup> Paul Edward Geller, 'An International Patent Utopia?' (2003) 25 *European Intellectual Property Review* 515, 515.

<sup>182</sup> Jane Nielsen and Dianne Nicol, 'Pharmaceutical Patents and Developing Countries: The Conundrum of Access and Incentive' (2002) 13 *Australian Intellectual Property Journal* 21; Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (2002) 7.

agencies. There have also been similar issues raised in relation to patent law and infectious diseases, such as malaria, tuberculosis, and avian influenza.<sup>183</sup> Alarms have been also raised about access to anti-anthrax pharmaceutical drugs in the event of bio-terrorism.<sup>184</sup> There are important lessons to be learned from the outbreak of public health epidemics and national emergencies.

The race to patent the SARS virus provides a new lens through which to consider access to essential medicines. There have been fears expressed that prospective patent holders might prevent or limit access to diagnostics, vaccines and pharmaceutical drugs which are being developed by commercial companies to address the SARS virus. A number of commentators have drawn parallels between the search for the SARS virus and the hunt for HIV. Seth Shulman regrets that the race to patent HIV jeopardised medical and scientific research: 'There is no question that the fighting consumed time that could have been spent trying to combat the disease'.<sup>185</sup> Peter Yu draws hedged comparisons between the SARS virus epidemic and the issues over access to HIV/AIDS drugs:

HIV/AIDS drugs have created serious tension between developed and less developed countries. SARS has not yet reached the same level as the HIV/AIDS pandemic. Nor is it as widespread. Hopefully, it never will be. Still, if it remains a recurring and potentially lethal disease, SARS drugs will be profitable, and affordable access to these drugs will become a major concern — and perhaps a reasonable fear — for the future. What if SARS drugs are as unaffordable and inaccessible as HIV/AIDS drugs? Will less developed countries have the technological capacity to develop and produce SARS drugs they need? Will the global patent system be able to strike the balance between research and development initiatives and consumer costs?<sup>186</sup>

Yu concludes that 'whether we can prevent a SARS crisis and maintain a desirable international patent system will depend on whether we have fully learned these lessons'.<sup>187</sup>

There could, of course, be debate about whether drawing such parallels between the SARS virus and HIV/AIDS crisis are appropriate. Some might object that such comparisons are tenuous, and it is premature to make such predictions, given that patents have only been recently filed in respect of the SARS virus. However, a good case can be made that such concerns are reasonable. Hopefully, the policy of 'defensive patenting' by public research institutions will promote access to the genetic sequence of the SARS virus. Nonetheless, concerns remain that 'defensive patenting' can also be used to block access to essential technology. In any case, it will be difficult for public research institutions to guarantee access to downstream technologies. There is an

<sup>183</sup> Médecins Sans Frontières, *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases* (2001); Antony Taubman, *Public-Private Management of Intellectual Property for Public Health Outcomes in the Developing World* (2004); Debora MacKenzie, 'Vietnam Last on Vaccine List' (2004) 181 *New Scientist* 8; Julie-Anne Davies, 'Plague Fears', *The Bulletin* (Sydney, Australia), 10 February 2004, 8.

<sup>184</sup> David Resnik and Kenneth De Ville, 'Bioterrorism and Patent Rights: "Compulsory Licensure" and the Case of Cipro' (2002) 2(3) *The American Journal of Bioethics* 29.

<sup>185</sup> Seth Shulman, 'Thinking Like a Virus: The Success of a Global Network in Identifying the Severe Acute Respiratory Syndrome, or SARS Pathogen' (2003) 106 *Technology Review* 74.

<sup>186</sup> Yu, 'SARS and the Patent Race: An Introduction', above n 13.

<sup>187</sup> *Ibid.*

array of organisations and commercial companies developing a range of diagnostics, vaccines and pharmaceutical drugs to combat the SARS virus.<sup>188</sup> Biotechnology companies and pharmaceutical drug manufacturers have expressed a desire to exploit any patents on such products in order to recoup research and development costs. There are strong commercial imperatives to control access to such essential tests and medicines. It would be complacent to disregard such natural entrepreneurial instincts. It is therefore prudent to ensure that the international patent system facilitates access to any future tests and medicines in respect of the SARS virus.

#### A The World Trade Organization

The WTO has been a key collective actor in the debate over patent law and access to essential medicines.<sup>189</sup> The *TRIPS Agreement* requires WTO Members to establish minimum standards for protecting and enforcing intellectual property rights.<sup>190</sup> Article 8 of the *TRIPS Agreement* declares:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

The *TRIPS Agreement* contains a number of provisions designed to promote the public interest in the field of public health. It allows governments to provide for exceptions, exclusions and limitations to rights, such as in the case of national emergencies, public non-commercial use, or remedying anti-competitive practices. This can be done, for example, in the form of compulsory licensing, exhaustion regimes and other types of exceptions, provided certain conditions are fulfilled. The *Doha Declaration on the TRIPS Agreement and Public Health* affirmed that WTO members could take measures to protect public health and promote access to essential medicines.<sup>191</sup> In particular, it recognised the gravity of the health problems afflicting many developing and least-developed countries, especially those resulting from epidemics such as HIV/AIDS. The WTO reached further agreement on the implementation of para 6 of the *Doha Declaration on the TRIPS Agreement and Public Health*, which deals with compulsory licensing for member states without manufacturing capabilities.

#### 1 Scope of Diseases

There has been some heated debate over the scope of the diseases which would be covered by the *Doha Declaration on the TRIPS Agreement and Public Health* on access to essential medicines. Article 1 of the *Doha Declaration on the TRIPS Agreement and Public Health* acknowledges: 'We recognize the gravity of the public health problems afflicting many developing and

<sup>188</sup> For an example of a vaccine, see Zhi-Yong Yang et al, 'A DNA Vaccine Induces SARS Coronavirus Neutralization and Protective Immunity in Mice' (2004) 428 *Nature* 561.

<sup>189</sup> Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis* (2<sup>nd</sup> ed, 2003) 52; Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (2003) 43.

<sup>190</sup> *TRIPS Agreement*, above n 19.

<sup>191</sup> *Doha Declaration on the TRIPS Agreement and Public Health*, above n 20.

least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'. Article 4 stresses:

We agree that the *TRIPS Agreement* does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the *TRIPS Agreement*, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the *TRIPS Agreement*, which provide flexibility for this purpose.

Article 5(c) recognises that 'each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency' and it acknowledges 'that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency'.

Initially, the US argued that compulsory licensing should be restricted to a handful of infectious diseases — such as AIDS, tuberculosis, malaria and 'other epidemics of comparable gravity and scale'. On 20 December 2002, the US drafted a footnote dealing with trade of generic medicines to countries with little or no manufacturing capacity. It extended the scope of diseases to 22 infectious diseases:

This decision applies to public health problems arising from yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, HIV/AIDS, leishmaniasis, TB, malaria, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, haemorrhagic fevers, and arboviruses and other epidemics of comparable gravity and scale including those that might arise in the future whether due to natural occurrence, accidental release or deliberate use.<sup>192</sup>

The US was criticised for renegeing on the *Doha Declaration on the TRIPS Agreement and Public Health*, and acceding to the demands of major pharmaceutical drug companies — such as the Pfizer Corporation.<sup>193</sup> Significantly, the list of diseases failed to include many major public health problems in developing countries.

<sup>192</sup> *Notes on the Scope of Diseases to be Covered in the Paragraph Six 'Solution'*, 20 December 2002 [4] <<http://www.cptech.org/ip/wto/p6/scope.html>> at 1 October 2004.

<sup>193</sup> Mary Moran, Médecins Sans Frontières, *Reneging on Doha: An MSF Analysis of Recent Attempts to Restrict Developing Countries' Use of Compulsory Licensing to a Set List of Diseases* (2003).



On 7 January 2003, the European Union offered a longer list of diseases that expanded upon the US footnote, and proposed a mechanism for review. It stated:

This covers at least HIV/AIDS, malaria, tuberculosis, yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, leishmaniasis, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, haemorrhagic fevers and arboviruses. When requested by a Member, the World Health Organization shall give its advice as to the occurrence in an importing Member, or the likelihood thereof, of any other public health problem.<sup>194</sup>

In a report to the Cancún discussions of the WTO, Jean Bizet of France discussed the ambiguity of the *Doha Declaration on the TRIPS Agreement and Public Health*. He argued that the reference to ‘other epidemics’ in the text was vague, and open to competing interpretations amongst the member states: ‘In the French version, the word “*épidémies*” supports the notion of contagion while in English *epidemics* could also include diabetes or mental illness’.<sup>195</sup> This linguistic criticism is unconvincing. The definition of ‘epidemics’ was always intended to be open-ended and Bizet’s focus on the etymology of the word ‘epidemic’ is therefore unhelpful.

The US and EU revised proposals have been supported by pharmaceutical drug companies and their allies. Robert Goldberg, the director of the Center for Medical Progress at the Manhattan Institute in New York, maintains that drug patents should not be overridden by compulsory licensing:

The enemies of medical progress want to call a cease-fire in the war against human suffering. We can’t afford not to fight back. A host of afflictions — from depression to AIDS, from SARS to bioterrorism — continue to demand our attention. Policies that control prices, limit access, and weaken patent protection threaten us all.<sup>196</sup>

The director argues that strong patent protection for pharmaceutical drugs is necessary to combat health emergencies — such as AIDS, SARS and bio-terrorism.

The US and the EU have been criticised for their view that the scope of the *Doha Declaration on the TRIPS Agreement and Public Health* should be restricted to a shortlist of diseases. Their position has come under attack from consumer groups, aid organisations and developing countries. Sanjay Basu comments on the conduct of the US Trade Representative (‘USTR’):

At the top of a long list of ironies is the fact that the USTR’s list of diseases for which generic drugs can be produced excludes the severe acute respiratory syndrome (SARS) — which of course, didn’t exist publicly until after the USTR had produced his list. This highlights the importance of keeping the *Doha Declaration* in its original form — whereby health ministries can tackle an epidemic as it occurs rather than waiting for their populations to die and spread the disease to wealthier nations which have the generic manufacturing capacity to

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<sup>194</sup> Consumer Project on Technology, *EU Draft Proposal for a Compromise Solution* (2003) <<http://www.cptech.org/ip/wto/p6/eu01072003.html>> at 1 October 2004.

<sup>195</sup> Jean Bizet, ‘The *TRIPS Agreement* and Public Health’ (Speech Delivered at the parliamentary conference on the WTO, Cancún, Mexico, 9, 12 September 2003).

<sup>196</sup> Robert Goldberg, ‘Health-Care Symposium: The Suffocation of Innovation’ (2003) 55(12) *National Review* 29, 30.

actually control it (and this is particularly important in the case of SARS, for which genome components and potential therapeutic agents are already being patented).<sup>197</sup>

In contrast, India has found favour with its position that a broad, open-ended definition of diseases should be adopted.<sup>198</sup> Countries affected by the SARS virus such as Singapore have supported this stance: 'The spreading killer flu made it imperative for authorities to make medicines accessible at reasonable prices'.<sup>199</sup> The emergence of avian influenza also reinforced the need for an open-ended definition of infectious diseases.

## 2 Export of Pharmaceutical Drugs

Article 6 of the *Doha Declaration on the TRIPS Agreement and Public Health* provides:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the *TRIPS Agreement*. We instruct the Council for *TRIPS* to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

In the lead up to the Cancún meeting on 30 August 2003, WTO member governments reached an agreement on the implementation of para 6 of the *Doha Declaration on the TRIPS Agreement and Public Health*. This paragraph calls for a solution to compulsory licensing for member states without manufacturing capabilities.<sup>200</sup> The agreement allows any member country to export pharmaceutical products made under compulsory licences within the terms set out in the decision. All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will *not* use the system to import. The decision covers patented products or products made using patented processes in the pharmaceutical sector, including active ingredients and diagnostic kits.

In November 2003, the new Canadian Prime Minister, Paul Martin, announced the introduction of a new Bill to provide low cost drugs to fight AIDS in developing countries. He dubbed the legislation, the 'Jean Chrétien Pledge to Africa Act',<sup>201</sup> to honour his predecessor's initiatives in that area. Martin observed:

<sup>197</sup> Sanjay Basu, 'Patents and Pharmaceutical Access', *ZNet*, 29 May 2003 <<http://www.zmag.org/content/showarticle.cfm?ItemID=3694>> at 1 October 2004.

<sup>198</sup> P Jyothi Datta, 'SARS Strengthens Case for Drugs at Affordable Cost — Singapore, Others May Join India's Stand at WTO', *Hindu Business Line: Internet Edition* (New Delhi, India), 13 May 2003 <<http://www.blonnet.com/bline/2003/05/13/stories/2003051302470400.htm>> at 1 October 2004.

<sup>199</sup> *Ibid.*

<sup>200</sup> General Council, 'Implementation of Paragraph 6 of the Doha Declaration on the *TRIPS Agreement* and Public Health', WTO Doc WT/L/540 (2003) <[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)> at 1 October 2004.

<sup>201</sup> *An Act to Amend the Patent Act and the Food and Drugs Act*, SC 2004, c 23.

The world needs our values. The world needs us now. That is why we will be the first country in the world with legislation to open the door to increased export and production of patented medicines to help people suffering from HIV/AIDS, malaria and TB, among other diseases, in the developing world.<sup>202</sup>

This statute amends the *Patent Act*<sup>203</sup> and the *Food and Drugs Act*<sup>204</sup> 'to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics'.<sup>205</sup> These amendments were introduced to implement para 6 of the *Doha Declaration on the TRIPS Agreement and Public Health*. The legislation was passed by the Canadian Parliament and received Royal Assent in May 2004.

It would be interesting to see whether this legislation could be invoked in the wake of another public health epidemic in respect of the SARS virus. If so, pharmaceutical drugs, vaccines, and diagnostics being developed in relation to the SARS virus could be exported to developing countries in such circumstances.

### B The World Health Organization

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as 'one of the biggest success stories in public health in recent years'.<sup>206</sup> However, it was less active in the debate over patent law and public health epidemics. The 56<sup>th</sup> World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed

that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.<sup>207</sup>

However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of aspirational statements about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate.

Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency did not even seem aware of the patent proceedings, leaving individual research institutions without guidance.

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<sup>202</sup> Paul Martin, 'Confederation Dinner' (2003) <[http://www.paulmartin.ca/home/stories\\_e.asp?id=886](http://www.paulmartin.ca/home/stories_e.asp?id=886)> at 9 December 2003. This page is no longer available (copy on file with author.)

<sup>203</sup> *Patent Act*, RSC 1985, c F-27.

<sup>204</sup> *Food and Drugs Act*, RSC 1985, c P-4.

<sup>205</sup> Canada, *Government Orders*, Edited Hansard No 044, 37<sup>th</sup> Canadian Parliament, 3<sup>rd</sup> Session, April 29 2004 (Charles Caccia, Davenport, Lib) <[http://www.parl.gc.ca/37/3/parlbus/chambus/house/debates/044\\_2004-04-29/han044\\_1345-E.htm](http://www.parl.gc.ca/37/3/parlbus/chambus/house/debates/044_2004-04-29/han044_1345-E.htm)> at 1 October 2004.

<sup>206</sup> WHO, *The World Health Report 2003 — Shaping the Future* (2003) 71–82.

<sup>207</sup> WHO, 56<sup>th</sup> World Health Assembly, *Fourth Report of Committee A* (Draft) (2003) WHO Doc A56/66, 83–4 <[http://www.who.int/gb/ebwha/pdf\\_files/WHA56/ea5666.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA56/ea5666.pdf)> at 1 October 2004.

Spokesman Dick Thompson said: 'What we care about is [that] the international collaboration continues to function. Patents, they don't really concern us'.<sup>208</sup>

The director of WHO's Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: 'I don't think this will undermine the collaborative spirit of the network of labs'.<sup>209</sup> However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: 'At a certain point of time you have to give way for competitive pharmaceutical companies'.<sup>210</sup>

On a policy front, the WHO remained deferential to the WTO over the debate over patent law and access to essential medicines, observing:

Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.<sup>211</sup>

In such a statement, the WHO appears diffident, unwilling to take on more than a spectator role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the *TRIPS Agreement* on public health concerns.

The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the WHO should not be limited to a mere spectator role in such policy discussions. It needs to play an active advocacy role in the debate over patent law and access to essential medicines. The WHO released a position statement on 'Patent Applications for the SARS Virus and Genes' on 29 May 2003.<sup>212</sup> The organisation stressed that it

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<sup>208</sup> Elias, 'Race to Patent SARS Virus Renews Debate', above n 68.

<sup>209</sup> Regalado, above n 44.

<sup>210</sup> Ibid.

<sup>211</sup> WHO and WTO, *WTO Agreements and Public Health: A Joint Study by the WHO and WTO Secretariats* (2002) 95.

<sup>212</sup> WHO, *Patent Applications for SARS Virus and Genes* (2003) <[http://www.who.int/ethics/topics/sars\\_patents/en](http://www.who.int/ethics/topics/sars_patents/en)> at 1 October 2004. Similar sentiments were expressed in Communicable Disease, Surveillance and Response, WHO, *Update 91 — SARS Research: The Effect of Patents and Patent Applications* (2003).

had no per se objection to the patenting of the SARS virus:

Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.<sup>213</sup>

Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research:

The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.<sup>214</sup>

The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.<sup>215</sup> The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed:

In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.<sup>216</sup>

However, the WHO expressed no opinion as to whether there should be any immediate reforms.

# 1 *The 56<sup>th</sup> World Health Assembly*

The 56<sup>th</sup> World Health Assembly<sup>217</sup> considered a report on ‘Intellectual Property Rights, Innovation and Public Health’ prepared by the Secretariat of the

<sup>213</sup> WHO, *Patent Applications for SARS*, above n 212.

<sup>214</sup> Ibid.

<sup>215</sup> Ibid.

<sup>216</sup> Ibid.

<sup>217</sup> WHO, *Fourth Report of Committee A* (Draft), above n 207, 3–4.

WHO.<sup>218</sup> It maintained

that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.<sup>219</sup>

The Assembly requested that

the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the *Doha Declaration* which promotes and encourages technology transfer.<sup>220</sup>

The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.<sup>221</sup> It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.<sup>222</sup> The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.<sup>223</sup>

The Director-General of the WHO, Dr Gro Harlem Brundtland, told the World Health Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation is a critical challenge — whether the target is SARS or any other threat to human health’.<sup>224</sup> Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said:

If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.<sup>225</sup>

She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure

<sup>218</sup> WHO, 56<sup>th</sup> World Health Assembly, *Intellectual Property Rights, Innovation And Public Health: A Report by the Secretariat*, WHO Doc A56/17 (2003) <[http://www.who.int/gb/ebwha/pdf\\_files/WHA56/ea5617.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA56/ea5617.pdf)> at 1 October 2004.

<sup>219</sup> WHO, *Fourth Report of Committee A* (Draft), above n 207, 3–4.

<sup>220</sup> Ibid 4.

<sup>221</sup> Ibid 9–11.

<sup>222</sup> Ibid 9.

<sup>223</sup> Ibid 11.

<sup>224</sup> Gro Harlem Brundtland, ‘Address to the 56<sup>th</sup> World Health Assembly’ (Speech delivered at the 56<sup>th</sup> World Health Assembly, Geneva, 18 May 2003) <<http://www.who.int/dg/speeches/2003/wha56speech/en>> at 1 October 2004.

<sup>225</sup> UN News Centre, *SARS Vaccine Trial Could Start in a Few Months — WHO* (2003) <<http://www.un.org/apps/news/story.asp?NewsID=8785&Cr=sars&Cr1=&Kw1=SARS+vaccine&Kw2=&Kw3=>>> at 1 October 2004.

that, once developed, they are available in both industrialised and developing countries.<sup>226</sup>

### C Summary

The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on 'Intellectual Property Rights, Innovation, and Public Health'.<sup>227</sup> He maintains that the Assembly could have addressed 'practical examples, like SARS' and cites the report in *The Washington Post* that notes that a number of commercial companies are investing in SARS research.<sup>228</sup> The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: 'As the world's leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should do much more'.<sup>229</sup> The WHO should become a vocal advocate for public health concerns at the WTO and its *TRIPS* Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines.

### V CONCLUSION

The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as 'defensive patenting' — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus:

The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more

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<sup>226</sup> Ibid.

<sup>227</sup> James Love, *WHO on Intellectual Property Rights, Innovation and Public Health* (2003) Essential Drugs.org, 1–3 <<http://www.essentialdrugs.org/edrug/archive/200305/msg00047.php>> at 1 October 2004.

<sup>228</sup> Ibid.

<sup>229</sup> Médecins Sans Frontières, 'Access to Essential Medicines: Can the World Health Organization Do More?' (2001) <<http://www.accessmed-msf.org/upload/ReportsandPublications/2920012359554/WHA%20Briefing%20note%20ENGLISH.pdf>> at 1 October 2004.

like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.<sup>230</sup>

There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus.

There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, '[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application'.<sup>231</sup> There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry.

The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate over patent law and access to essential medicines. Not only could it mediate legal disputes over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the *Doha Declaration on the TRIPS Agreement and Public Health*.

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<sup>230</sup> Shulman, above n 185, 74.

<sup>231</sup> Yu, 'SARS and the Patent Race: An Introduction', above n 13.



Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes:

SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20<sup>th</sup> century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.<sup>232</sup>

Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.<sup>233</sup> There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.<sup>234</sup>

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<sup>232</sup> WHO, *The World Health Report 2003*, above n 206, 81.

<sup>233</sup> Clive Cookson et al, 'Thailand Reports First Case of Bird Flu in People: Health Alert', *Financial Times* (London, UK), 24 January 2004, 7; Debora MacKenzie, 'Vietnam Last on Vaccine List' (2004) 181 *New Scientist* 8; Robert Walgate, 'H5N1 Vaccine Strain in a Week', *The Scientist*, 29 January 2004 <<http://www.biomedcentral.com/news/20040129/05>> at 1 October 2004.

<sup>234</sup> For a discussion of the frequent appearance of new infectious diseases, see Pete Moore, *Super Bugs: Rogue Diseases of the Twenty-First Century* (2001).